HITSP Harmonization Framework and Exchange Architecture Technical Note

HITSP/TN904

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1.0 INTRODUCTION

This Technical Note describes the Harmonization Framework as amended by the Healthcare Information Technology Standards Panel (HITSP) on June 30, 2009. This amended Framework is intended to address issues in the construction and use of the HITSP artifacts.

The Harmonization Framework and Exchange Architecture Technical Note (TN) defines the terms, concepts, relationships, and associations that are realized in the artifacts that comprise the primary work product of the Panel, e.g., an Interoperability Specification (IS), Capability (CAP), Component (C), Transaction (T), Transaction Package (TP) and Service Collaboration (SC). Further, it organizes the terms and concepts into a HITSP model based on information exchanges specific to data, context, business process, and workflow.

The IS development process is accomplished by conducting a requirements analysis of the target functional needs or capabilities in term of data flows and process work flows performed by systems, which support stakeholders. This results in identifying Information Exchange Requirements (IERs) including Data Requirements (DRs) needed to meet stakeholder needs and enable interoperability. These Information Exchange Requirements are then specified by selecting the Capabilities or supporting Service Collaborations, Transaction Packages, Transactions, and Components. The Harmonization Framework describes a classification of standards, regulatory guidance, selected standards and informative references. These concepts and others form the HITSP Harmonization Framework which is described in this document.

The Exchange Architecture part of this Technical Note defines the fundamental topologies that can be used in implementing the HITSP Interoperability Specifications in configurations such as Electronic Health Record (EHR) systems directly connected to each other or connected to Health Information Exchanges (HIEs), which may be connected to the NHIE.

HITSP documents are targeted to HITSP members, stakeholders and users, which include executives, managers, analysts and implementers. To support this wide audience, this document and other HITSP documents address requirements and design separately, with a drill down from concept to technical details, and specialized material contained in separate sections.

For each reader of this document, there is a suggested reviewing road map as follows:

1. Executives, Functional Analysts and Implementers, who want a general understanding of the framework may want to review:
   – Section 1.0 through Section 3.0 which presents a high level overview of the framework
2. Implementers and other readers who want a detailed understanding and examples of the framework may want to review:
   – Section 4.0 HITSP Harmonization Framework Technical View, which provides detailed information about technical aspects of the framework[1]
   – Section 5.0 presents examples of the HITSP Exchange Architecture, providing concrete examples of applying the framework
   – Section 6.0 and 7.0 explain Standards Types and Categories that define reference types for HITSP Constructs and Usage Declarations for terms used in this TN. These sections are for the reader who wants to gain a deeper technical understanding of this TN

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[1] A separate spread sheet and/or database, is available at hitsp.org, contains the value sets of the HITSP Exchange Architecture set of Exchange Actions, Exchange Contents, Systems, and their mapping to the 13 legacy Interoperability Specification (IS) Information Exchange Requirements (IERs).

2.0 KEY DEFINITIONS

Following is a list of the key HITSP terms and definitions, listed in the order they are used within this Technical Note:

Harmonization Framework: defines the terms, concepts and their relationships within a HITSP Interoperability Specification (IS), Capability (CAP), Component (C), Transaction (T), Transaction Package (TP) and Service Collaboration (SC).

Exchange Architecture: defines the fundamental topologies that can be used in implementing the HITSP Interoperability Specifications in systems (e.g., EHR systems directly connected or connected to Health Information Exchanges (HIEs) and HIEs connected to other HIEs.

Capability (CAP): is an implementable business service that specifies interoperable Information Exchanges using HITSP constructs. A Capability supports stakeholder requirements and business processes and includes workflow, information content, infrastructure, Security and Privacy.

Harmonization Request: defines business or functional needs, within a workflow, and sets context and conditions for the Interoperability Specification. Behavioral specifications of functional needs or capabilities may be structured as Use Cases, Scenarios, Business Process Models or other forms.

Stakeholder: is defined as a person or organization that uses or benefits from systems that interoperate.

Construct: is a specification based on harmonized interoperability standards. HITSP defines Transaction, Transaction Package, Service Collaboration and Component constructs.

Interoperability Specification (IS): is organized by scenarios, Capabilities and integrates and constrains HITSP Constructs to specify the interoperability needs of one or more business processes.

System[2]**:** is an IT software application that plays an initiating or responding role in one or more Information Exchanges addressed by a HITSP Interoperability Specification or Capability.

Transaction (T): is a logical grouping of data exchanges and transport methods that must all succeed or fail as a group. Examples are the Query Lab Result or Send Lab Result.

Transaction Package (TP): is a logical grouping of two or more Transactions, Transaction Packages, and/or composite standards used to fulfill Information Exchange Requirements (**IERs**). A Transaction Package is not required to succeed or fail as a whole. Examples include the Record Locator Service and Entity Identification Service.

Component: is a construct that defines the set of data elements, structures, relationships, constraints and terminology needed to support specific reusable information content. A Component may also express constraints on base or composite standards, examples include the Lab Result Message and Lab Result Document.

Service Collaboration (SC): is the composition of HITSP Transaction, Transaction Package, or Component constructs into a reusable workflow, primarily at the infrastructure level, for example HITSP/SC115 HL7 Messaging Service Collaboration.

Interface[3]: is the set of features and obligations that support Information Exchanges for a HITSP system. Interfaces and Information Exchanges between interfaces are specified by HITSP

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[2] previously known as Business Actor

[3] previously known as Technical Actor

Constructs, including Service Collaborations for example, Content Creator, Document Consumer, Eligibility Information Receiver and Audit Record Repository.

Base Standard: is a standard capable of fulfilling a discrete function within a single category produced and maintained by a single standards organization. **Examples** include HL7 v2.x, SNOMED-CT.

Composite Standard: is a grouping of coordinated base standards, often from multiple standards organizations, maintained by a single organization. Examples include IHE Information Technology Infrastructure XDS Integration Profile.

Data Requirement (DR): defines requirements for all or part of the IER exchange content as a set of data elements with specific semantic details.

Information Exchange Requirement (IER): is a business requirement described in terms of Exchange Content, Exchange Action, Systems involved in the exchange and Exchange Attributes.

- **Exchange Content:** describes the information to be communicated in business terms
- **Exchange Action:** describes the interaction that communicates the Exchange Content between the Systems
- **Exchange Attributes:** are parameters about an Information Exchange. Examples are constraints, conditions and triggers
- **IER Identifier** IER Identifier is an optional IER name and number, which is local to an IS and valid within the scope of an IS

3.0 CONCEPTUAL VIEW OF HITSP HARMONIZATION FRAMEWORK

This section describes how the HITSP documents support the Harmonization Framework. The HITSP Interoperability Specification (**IS**) provides context and constraints and orchestrates HITSP Capabilities and Constructs. An IS can be organized by scenarios to specify the interoperability needs of one or more business processes. The IS contains a requirements analysis, a design specification and selected standards and gaps. IS are of several types depending on the higher level business requirements. These include a Harmonization Request IS or a System-specific IS. One may visualize the relationship of IS and other constructs as shown in Figure 3-1.

Figure 3-1 Interoperability Specification Framework

Interoperability Specification and Capability

Constructs (SC, TP, T and C)

Base and Composite Standards

Interoperability Specification (Complete Set)
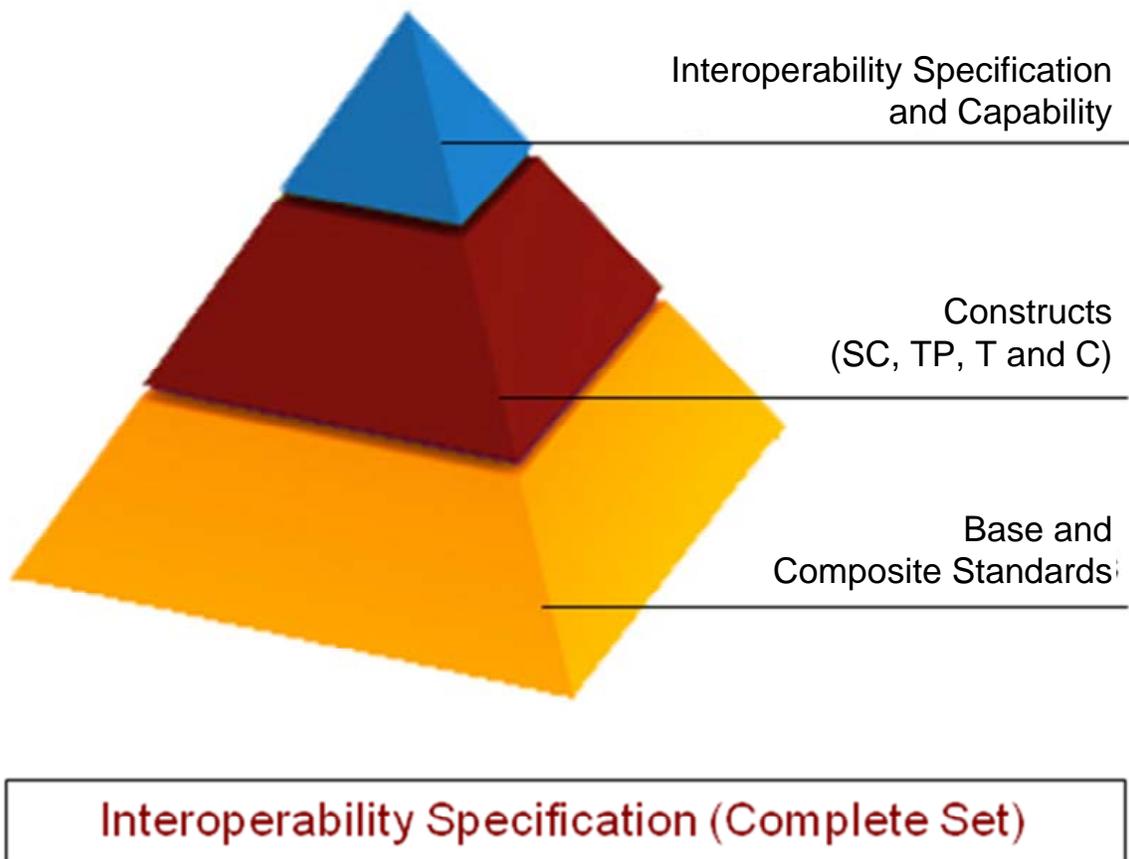
Figure 3-2 Fundamental Relationships depicts the interrelationships of the requirements and design sections of the IS. Stakeholders' Information Exchange Requirements (IERs) are met with System software Capabilities (**CAP**).

Figure 3-2 Fundamental Relationships
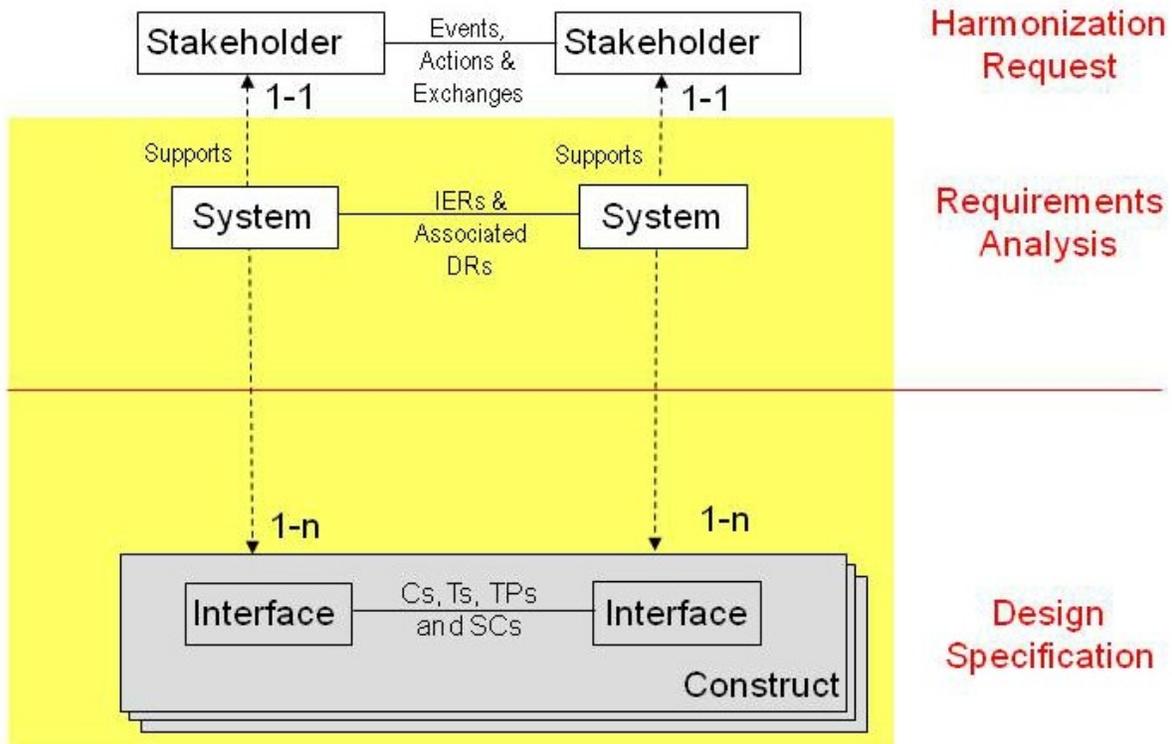
3.1 INTEROPERABILITY SPECIFICATION (IS)

Figure 3-3 HITSP Harmonization Framework illustrates the current framework. The shaded areas reflect two new constructs added in 2009 to simplify the use of the existing constructs. These are capabilities and Service Collaborations as previously describes. In the past the Interoperability Specification organized and constrained all constructs directly. Capabilities and Service Collaborations offer intermediate organization and constraints, freeing the Interoperability Specification of more detailed interface tables that limited reuse.

Figure 3-3 HITSP Harmonization Framework

Harmonization Request
Identifies interoperability business needs

Interoperability Specification

- Identifies what HITSP lower-level constructs to integrate to meet Business Needs
- Defines Requirements, Context and Constraints for those constructs

HITSP Capabilities

Service Collaborations

Transaction Constructs

Transaction Package

Transaction

Component

SDOs

| Base Standard #1 | Base Standard #2 | Base Standard #... | Base Standard #n | Composite Standard #1 | Composite Standard #... | Composite Standard #m |

3.1.1   HITSP INTEROPERABILITY SPECIFICATION REQUIREMENTS

As shown in Figure 3-4 HITSP IS Requirements are the unifying principles of HITSP IS requirements that an initiating System must execute a defined Exchange Action (EA), conveying a defined Exchange Content (EC), with one or more responding Systems, within a defined Topology. ECs and EAs in turn are satisfied by Capabilities. Capabilities support stakeholder requirements and business processes by providing a business service that is implementable. A Capability includes workflow, Information Exchanges, infrastructure, security and privacy. A Capability specifies system Information Exchange interoperability using Constructs.

Figure 3-4 HITSP IS Requirements
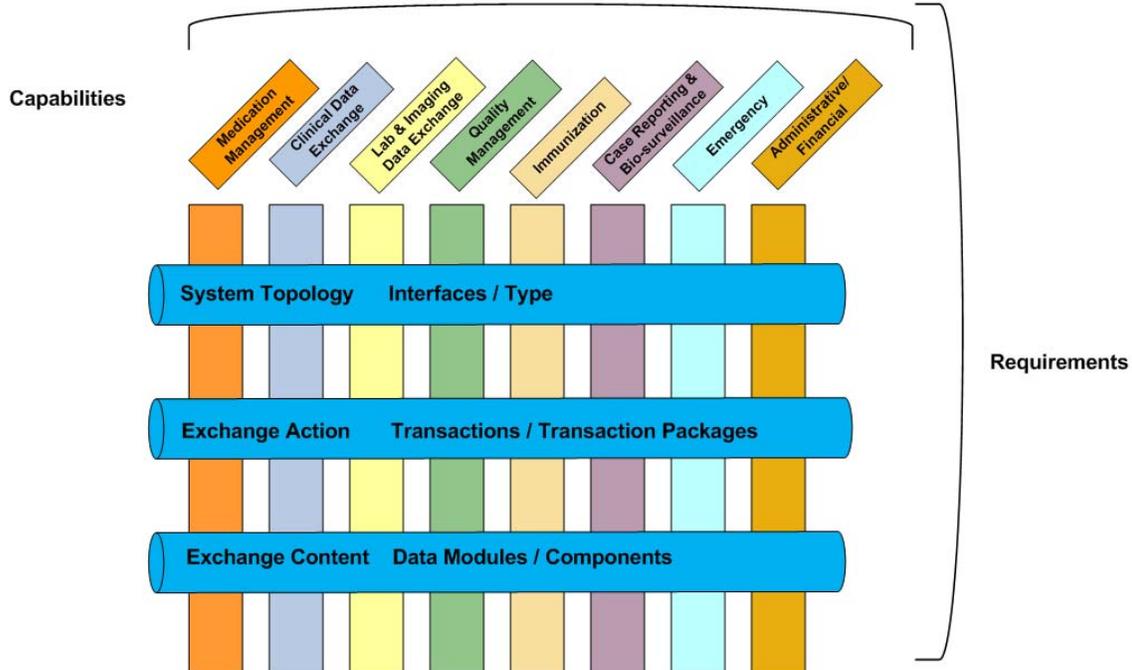
The following are examples of capabilities:

- CAP117: Communicate Ambulatory and Long Term Prescription
- CAP118: Communicate Hospital Prescription
- CAP119: Communicate Structured Document
- CAP120: Communicate Unstructured Document

3.1.2   HITSP IS DESIGN SPECIFICATIONS

HITSP Design Specifications include Capabilities, which orchestrate Service Collaboration (**SC**), Transaction (**T**), Transaction Packages (**TP**) and Components (**C**) to fulfill the requirements of

Figure 3-4 HITSP IS Requirements. SCs integrate HITSP Security, Privacy and Infrastructure (**SPI**) constructs and the HITSP Exchange Content is defined by the Data Architecture.

3.2   SERVICE COLLABORATION

A Service Collaboration is the composition of HITSP Transaction, Transaction Package, or Component constructs into a reusable workflow, primarily at the infrastructure level. Service Collaborations do not contain content, i.e., Data Elements. Service Collaborations are organized into an external view, i.e., outward facing interfaces, and an internal view that includes inward facing interfaces. Inward facing interfaces may call upon Transaction Packages, Transactions, Components, or other Service Collaborations. The Service Collaboration document illustrates one internal view diagram and sequence table for each service interface. The internal view diagrams are descriptive and the associated sequences are not mandatory. They may be affected by policy, chosen architecture, and implementation details. Conformance is measured against the underlying constructs. Security and Privacy constructs are incorporated into the infrastructure Service Collaborations as appropriate.

Examples of Service Collaborations are:

- HITSP/SC108 Access Control
- HITSP/SC110 Patient Identification Management
- HITSP/SC111 Knowledge and Vocabulary
- HITSP/SC112 Healthcare Document Management Data
- HITSP/SC113 Query for Existing Data
- HITSP/SC114 Administrative Transport to Health Plan
- HITSP/SC115 HL7 Messaging

3.3   SECURITY, PRIVACY AND INFRASTRUCTURE

Security and privacy of healthcare information is essential to the successful adoption of electronic health records and to deployment of HIEs. To this end, HITSP has built security and privacy into its infrastructure. The applicability of SAML, XACML and other related identity standards are being leveraged to the greatest extent, moving forward. HITSP has a security, privacy and infrastructure "layer" that securely exchanges the authentication context, authorization context, network and device context, user context and other contextual data contextual composition of converged services, called Service Collaborations (SCs), while adhering to pervasive policies and established trust. That is SCs include all necessary Security and Privacy constructs.

HITSP SCs and/or security, privacy and infrastructure constructs are added to the "Interoperability Specification Section 3: Design", rather than be included in the "Interoperability Specification Section 2: Requirements". Figure 3-5 Security, Privacy and Infrastructure Service Collaborations shows the integration layers of the SPI Service Collaborations. This serves to focus requirements analysis on functional need. Security and privacy are discussed in HITSP/TN900 Security and Privacy.

Figure 3-5 Security, Privacy and Infrastructure Service Collaborations
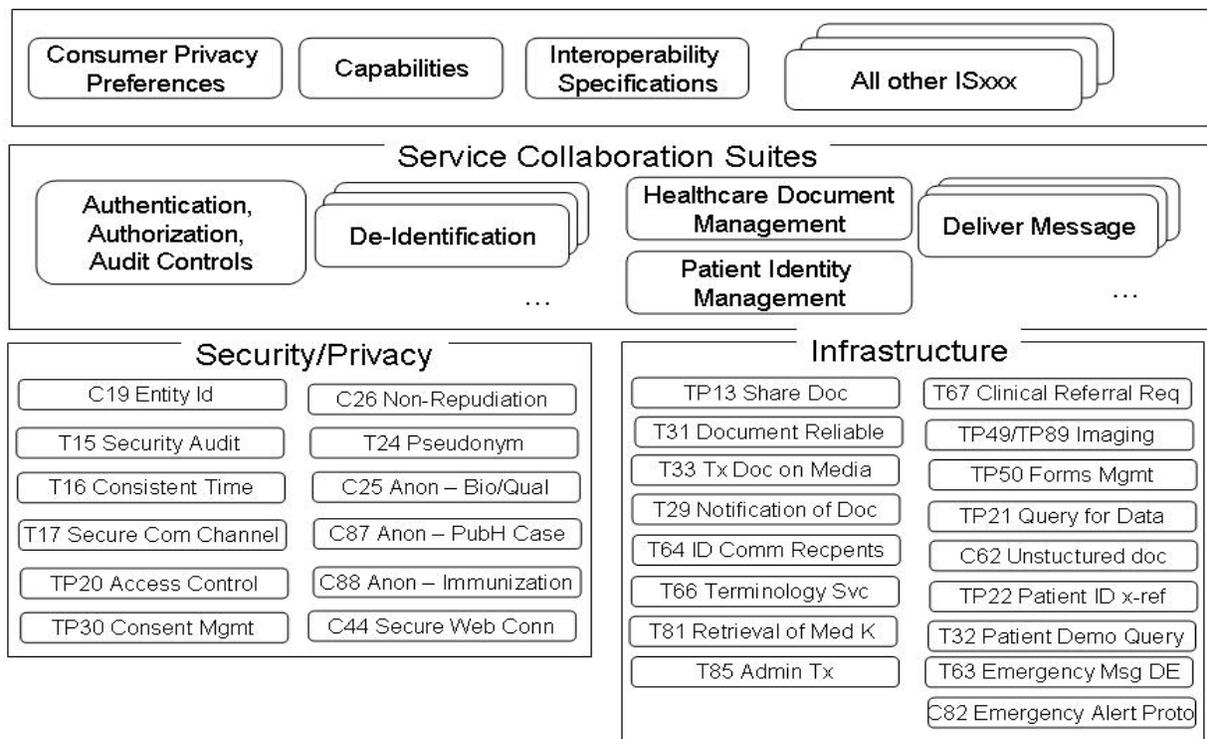
3.4   EXCHANGE ARCHITECTURE

The HITSP Exchange Architecture adds topology to the Harmonization Framework. Topology is the arrangement or mapping of networked Systems, especially the physical (real) and logical (virtual) interconnections between Systems. A Healthcare Information Exchange[4] (**HIE**) is a special network system that provides intermediary services, such as directories, registries or translations. Networks exhibit both a physical topology and a logical topology. Any given system in an HIE will have one-or-more interfaces to one-or-more other systems in the network and the mapping of the Interfaces and Systems onto a graph results in a geometrical shape that determines the <u>physical topology</u> of an Exchange Architecture. Likewise, the mapping of the Information Exchanges among the Systems in the network determines the <u>logical topology</u> of the Exchange Architecture.

The physical and logical topologies might be identical in any particular network; but, going from a HITSP IS to an actual HIE the logical and physical topologies are generally different.

Figure 3-6 Notional Exchange Architecture Topologies, provides a high level view of four implementation topology patterns of:

- Portable media (non-connected)
- System to system (point-to-point)
- System to HIE
- HIE to HIE

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[4] The terms "RHIO" and "Health Information Exchange" or "HIE" are often used interchangeably. An HIE is a more general instances of a RHIO (regional health information organization). Both are a grouping of organizations with a business stake in improving the quality, safety and efficiency of healthcare delivery. NHIEs are HIEs that support the building blocks of the National Health Information Network (NHIN) initiative proposed by the Office of the National Coordinator (ONC) for Health Information Technology (HIT). To build a national network of interoperable health records, the effort must first develop at the local and state levels. The concept of NHIN requires extensive collaboration by a diverse set of stake holders. The challenges are many to achieve success for a health Information Exchange or a RHIO [HIMSS].

Figure 3-6 Notional Exchange Architecture Topologies
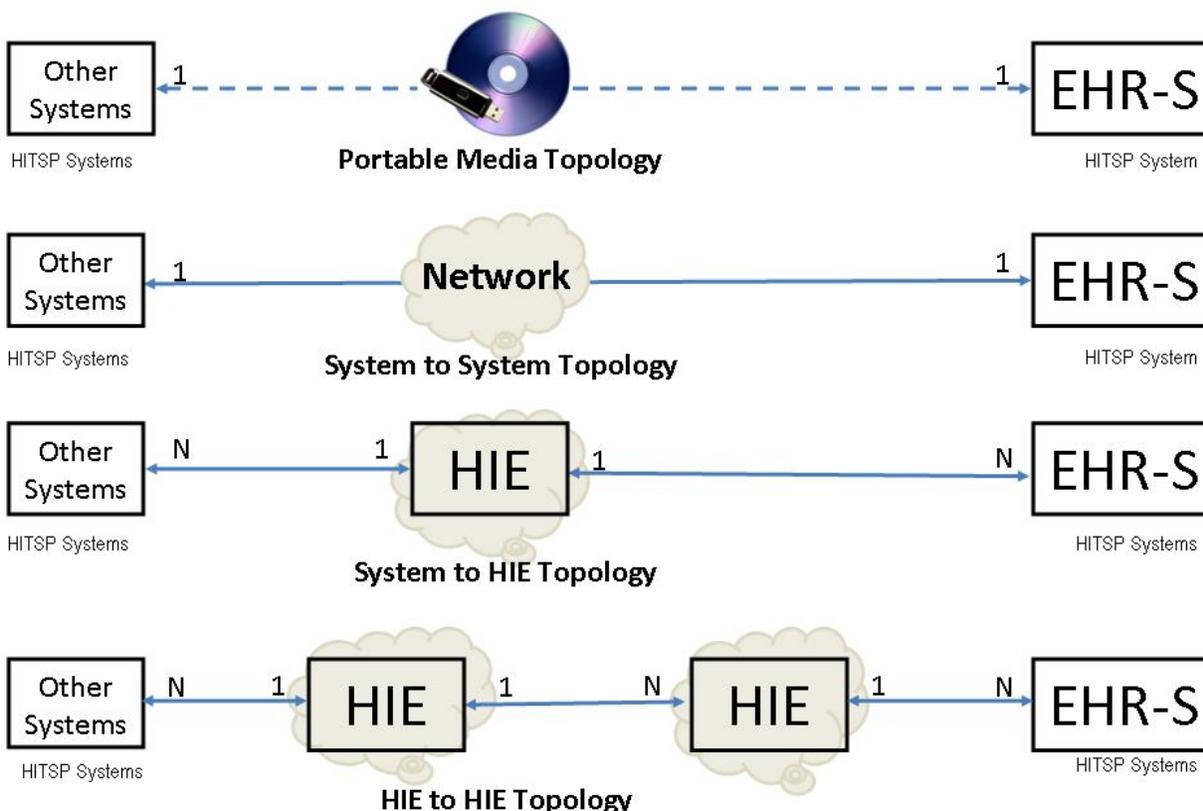
NOTE: HITSP Interoperability Specifications apply across business boundaries. An associated business agreement defines the business boundaries of EHRs, other systems and HIEs.

HITSP ISs apply to information exchanges indicated by the arrows in the figure.

These patterns can be combined to create any HIE combination as is shown in Figure 3-7 Exchange Architecture Instance of HITSP/IS04 Emergency Responder and further discussed in Section 5.2. It should be noted that HITSP Interoperability Specifications (ISs) apply to a Systems' interfaces and their Information Exchanges.

Figure 3-7 Exchange Architecture Instance of HITSP/IS04 Emergency Responder

Notional IS04 ER-EHR EA

CALIFORNIA HIE HARMONIZATION
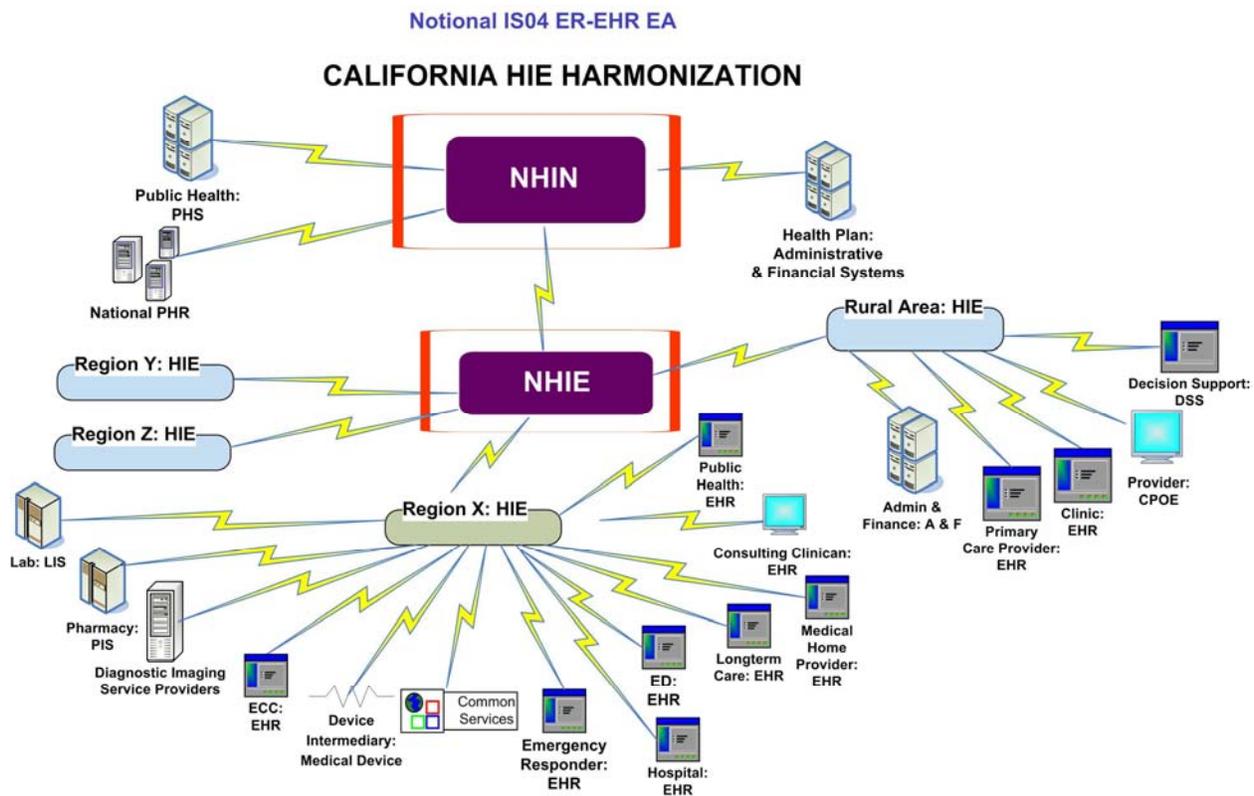
4.0 TECHNICAL VIEW OF HITSP HARMONIZATION FRAMEWORK

This section provides a model of the HITSP Harmonization Framework, using Unified Modeling Language (UML) class diagrams. We model a full HITSP Interoperability Specification (IS) and the simplified Harmonization Request IS, Capability Specification and System IS.

## 4.1 MODEL CONVENTIONS

Figure 4-1 UML Class Diagram Legend shows the model's conventions:

- **Bold dashed** connectors and **Bold** outlined classes indicate key Table content within HITSP Interoperability Specifications (IS) as discussed in Section 4.5.2
- Normal UML convention has lower case class attributes. To reduce diagram clutter, the NON UML convention of "a capitalized first letter class's Attribute indicates a UML aggregation or "realize" (aka "fulfilled") association with another class" (e.g., a design realizes or fulfills its requirements). This allows an architectural implementation instance to use object inheritance or delegation.
- A class element can instantiate multiple objects; hence classes are titled in the singular. Figure 4-1 UML Class Diagram Legend might be read as:
    - A Person drives a Car, which is-a vehicle; the vehicle has one-or-more Wheels;
    - A Vehicle depends on Fuel containing Gasoline and Alcohol (aka ethanol)
    - The Car fulfills a Design (e.g., Wheel specifications),
    - The Design fulfills a Requirement set (e.g., 2009 Chevrolet vehicle)
    - The Requirement set is "2009 Chevrolet wheeled vehicle, which uses ethanol fuel."
    - The design specifies that the 2009 Chevrolet Vehicle has 4 wheels

Figure 4-1 UML Class Diagram Legend
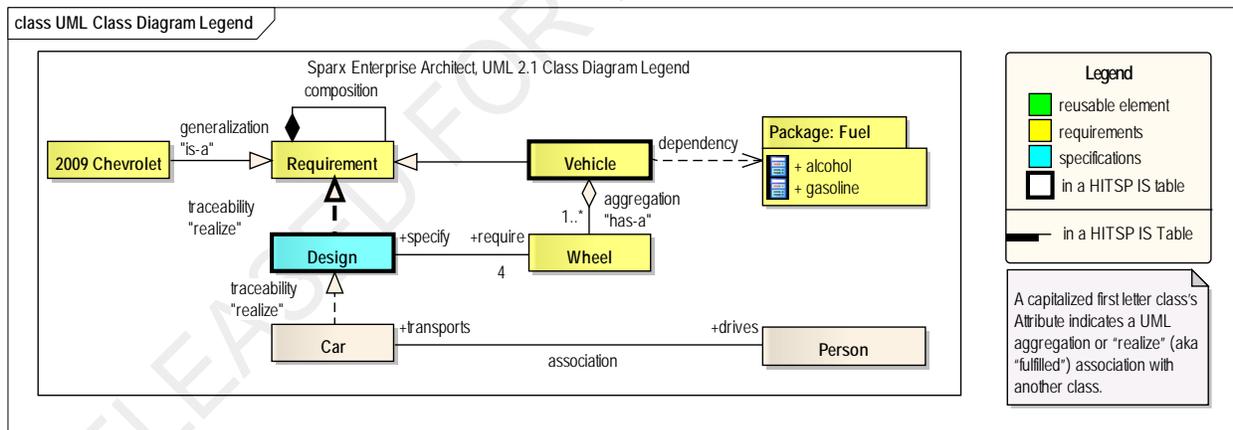
4.2 REUSE

Interoperability Specifications simplification through reuse is a major HITSP 2009 initiative. With this in mind, existing reusable HITSP constructs were augmented with reusable Requirements Level Exchange Contents, Exchange Actions, and Systems and a reusable Design Specification level Capabilities, Service Collaborations and a Data Architecture of Modules, Elements and Value Sets. Figure 4-2 Reusable Components shows how the new set of reusable Components fit into the Requirements, Design Specifications and Implementation phases.

Green model elements are reusable. They include Capability Specification, Capability, Exchange Action (EA), Exchange Content (EC), System, Component (C), Transaction (T), Transaction Package (TP), Service Collaboration (SC), Capability Specification, Selected Standard, Data Module, Data Element and Value Set.

Figure 4-2 Reusable Components
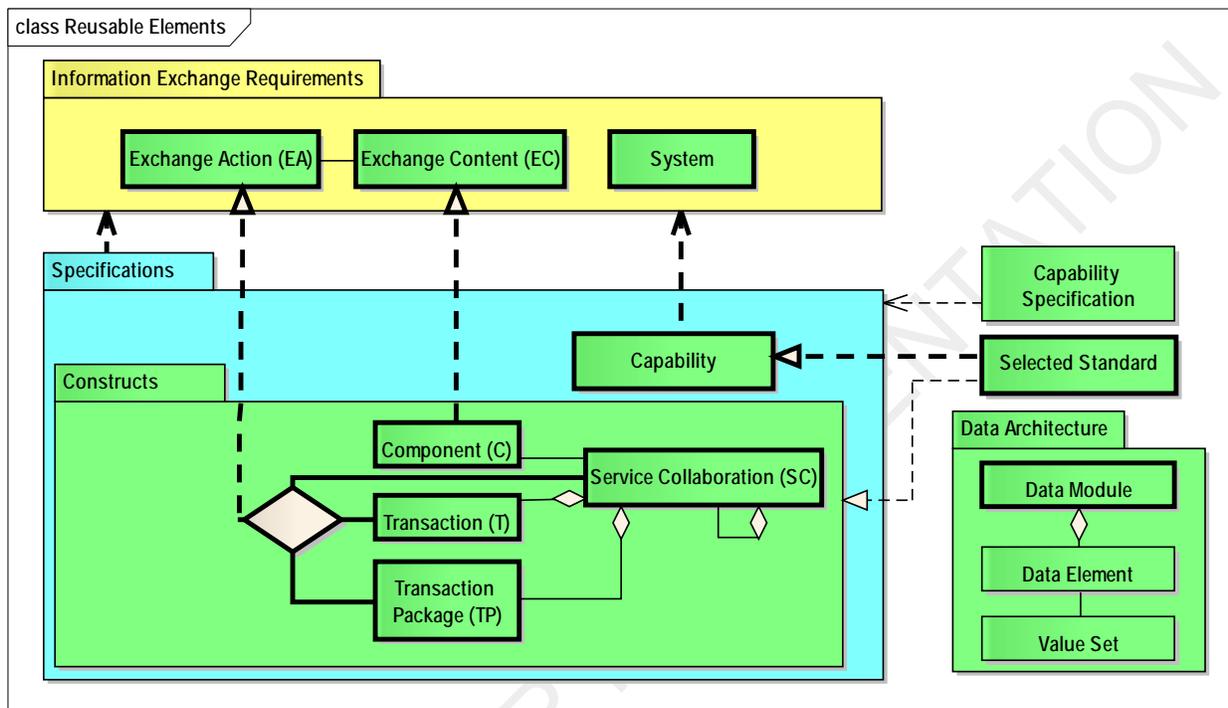
4.3   HARMONIZATION REQUEST

Generally, HITSP is provided some instance of Figure 4-3 Harmonization Request. A Harmonization Request is generally in the form of behavioral specifications, which provide the context and defines a Scenario's conditions. Requirements may be in the form of a Business Process description, a Use Case or other accepted format. Given this input, HITSP develops a Harmonization Request Interoperability Specification (IS). Historically the behavioral specification has been in the form of a Use Case, which contains Scenarios. Each Scenario is organized by Stakeholder (e.g., clinician, patient, etc.) or location (e.g., emergency department) perspectives (e.g., Business Processes). Each perspective is composed of a sequence of Events and Actions. Additionally, a Harmonization Request may contain descriptive information (e.g., data, issues, policy, comments) or may only contain Requirements (e.g., "Gaps and Extensions Harmonization Request"). Ideally, a Harmonization Request includes some form of description of the flow of Information among the Business Process' Stakeholders and their Systems.

Figure 4-3 Harmonization Request
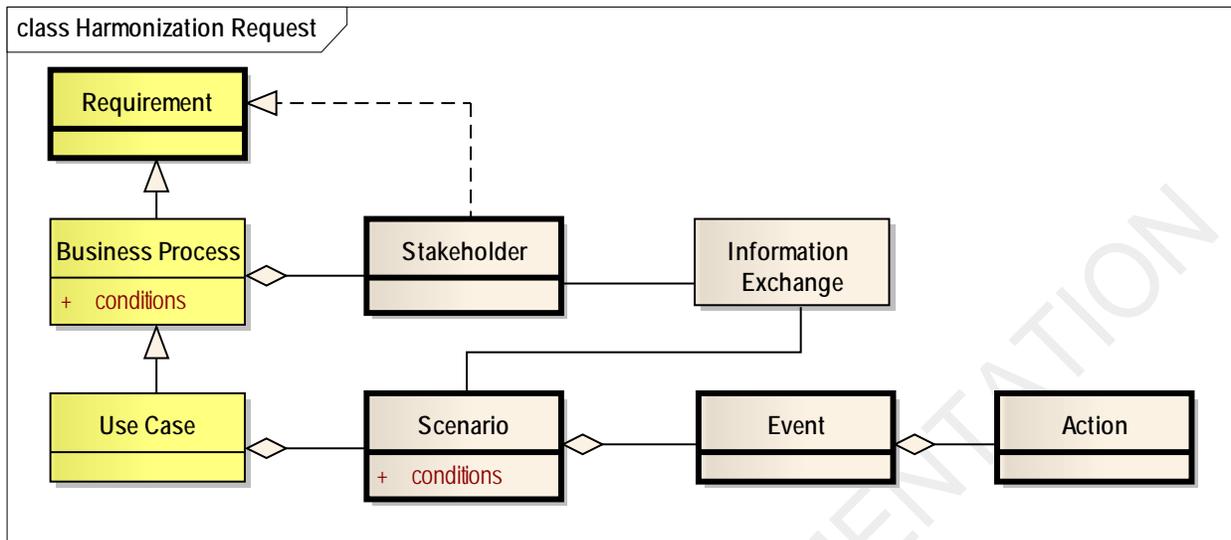
4.4 HITSP INTEROPERABILITY SPECIFICATION

HITSP has reorganized its artifacts to emphasize reuse, traceability and simplification. Since a HITSP Capability is in the interoperability space between Systems, an instance of the HITSP Exchange Architecture can be represented as a topology of system entities connected by their Capabilities. Capabilities are reusable across ISs. Each Capability specification can be provided within a System IS or in the future as a separate Capability Specification. To reduce IS volume; Capability Specifications may then be referenced, rather than included in a System or Harmonization Request IS. A particular System IS (e.g., EHR System IS) may be further abbreviated by only specifying the capabilities of that system, without regard to the systems with which it interacts.

On the left, Figure 4-4 HITSP IS Types shows the organization of a full IS. On the right, we can see that, since 2009, HITSP is producing the following streamlined Interoperability Specification types:

- Figure 4-5 Harmonization Request IS focuses on Requirements Analysis
- Figure 4-10 Capability Specification focuses on Design Specifications
- Figure 4-12 System IS focuses on the orchestration of Capabilities within a System

Figure 4-4 HITSP IS Types
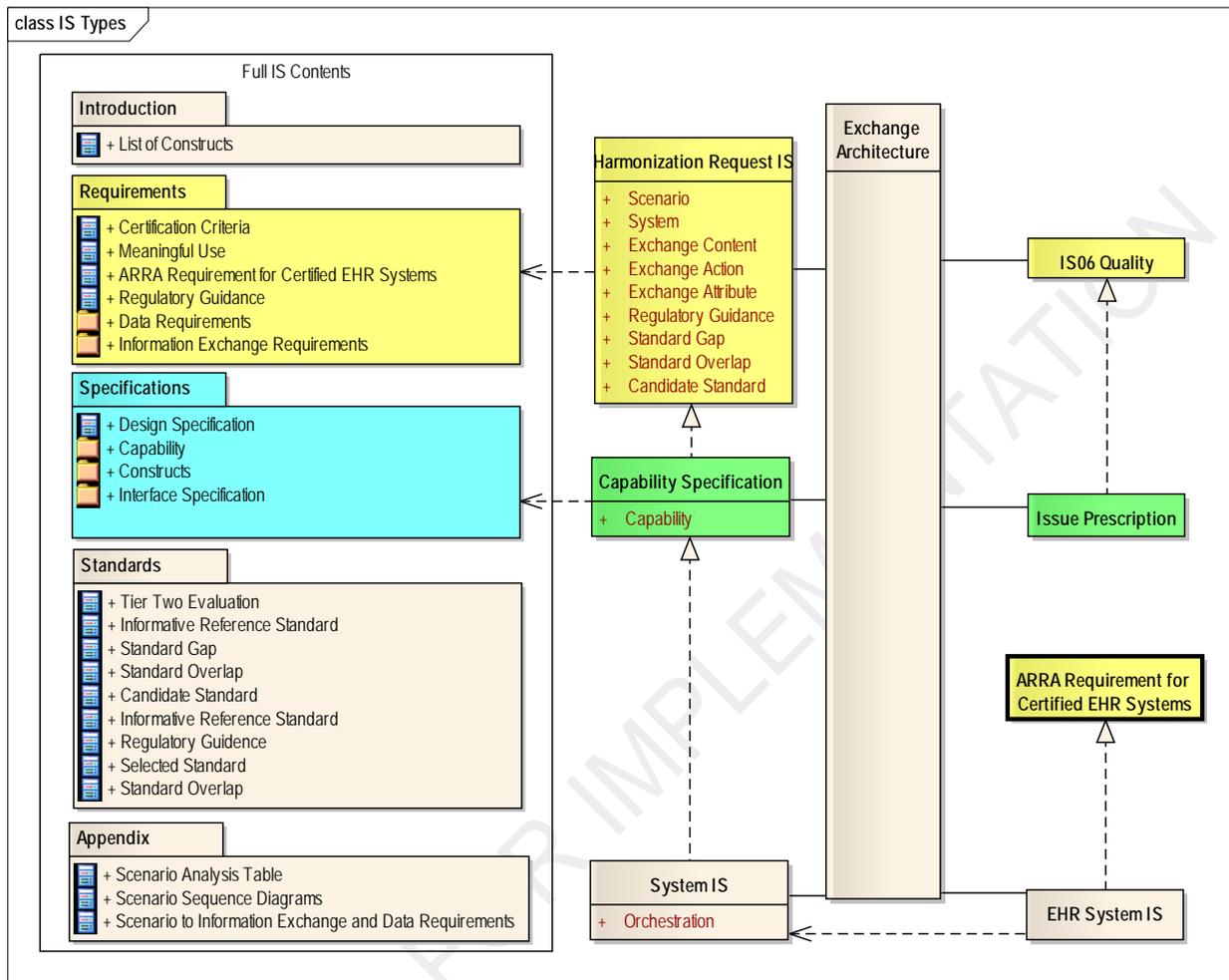
Table 4-1 Requirements vs. Specifications Views summarizes the key Requirements-Specifications relationships. Requirements are derived in a Harmonization Request IS as Exchange Content (EC), Exchange Action (EA), Exchange Attributes and Systems. Design Specifications are organized in a Capability Specification.

Table 4-1 Requirements vs. Specifications Views

Requirements-Analysis View	Design-Specification View
Pre 2009 IS Section 2: Requirements	Pre 2009 IS Section 3: Specifications
Information Exchange Requirement is composed of:	Capability Specification is composed of:
1. One Exchange Action Requirement mapped to 1-to-many to →	1. Exchange Action Specification is a Transaction, Transaction Package, or Service Collaboration
2. One Exchange Content Requirement mapped 1-to-1 to →	2. Exchange Content Specification is a Component or Transaction's message content
Exchange Content contains 1 or more specified Data Requirements	Components contain one or more specified Data Modules
Data Requirements mapped 1-to-1 to →	Clinical Data Modules in HITSP/C83 Component or Administrative and Finance type Modules
DR may contain granular Data Element Requirement by exception only	Data Modules contain Data Elements

4.4.1 HARMONIZATION REQUEST INTEROPERABILITY SPECIFICATION

After HITSP receives a Harmonization Request, a Harmonization Request IS documents the requirements analysis and provides traceability to the subsequent Capability Design Specifications. Figure 4-5 Harmonization Request IS shows that the requirements analysis results are expressed as Information Exchange Requirements (IERs), Data Requirements (DRs), Regulatory Guidance, Candidate Standards, Standards Gaps and Standards Overlaps. Each Scenario defines the IERs which will be fulfilled by some set of existing or new Capabilities, which are defined in associated Capability Specifications. The IER Exchange Attributes define the conditions and metadata for the Capability Design Specifications.

Figure 4-5 Harmonization Request IS
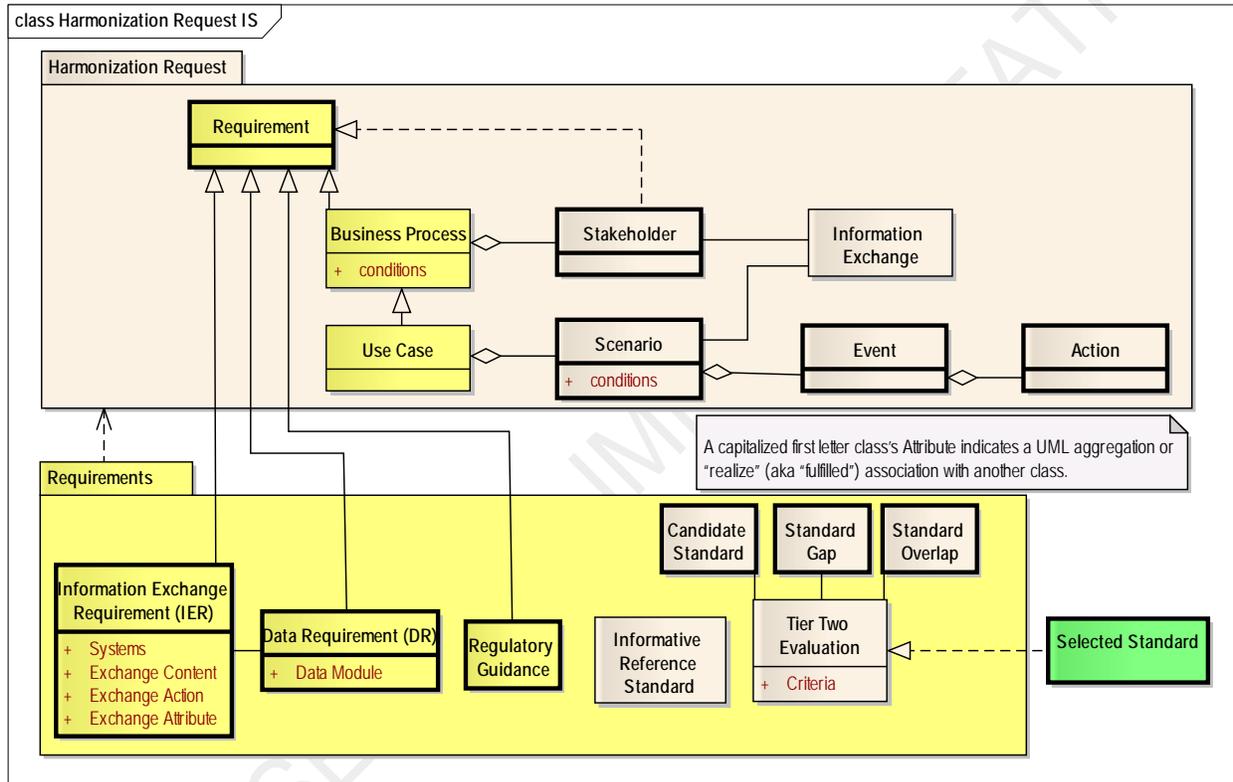
4.4.1.1 INFORMATION EXCHANGE REQUIREMENTS

Figure 4-6 IER-Capability Methodology Followed by HITSP shows an overview of HITSP's approach to meeting the American Recovery and Reinvestment Act (ARRA) Requirements for Certified EHR Systems and its meaningful use criteria defined by the ARRA Health IT Policy Committee.

**Figure 4-6 IER-Capability Methodology Followed by HITSP**
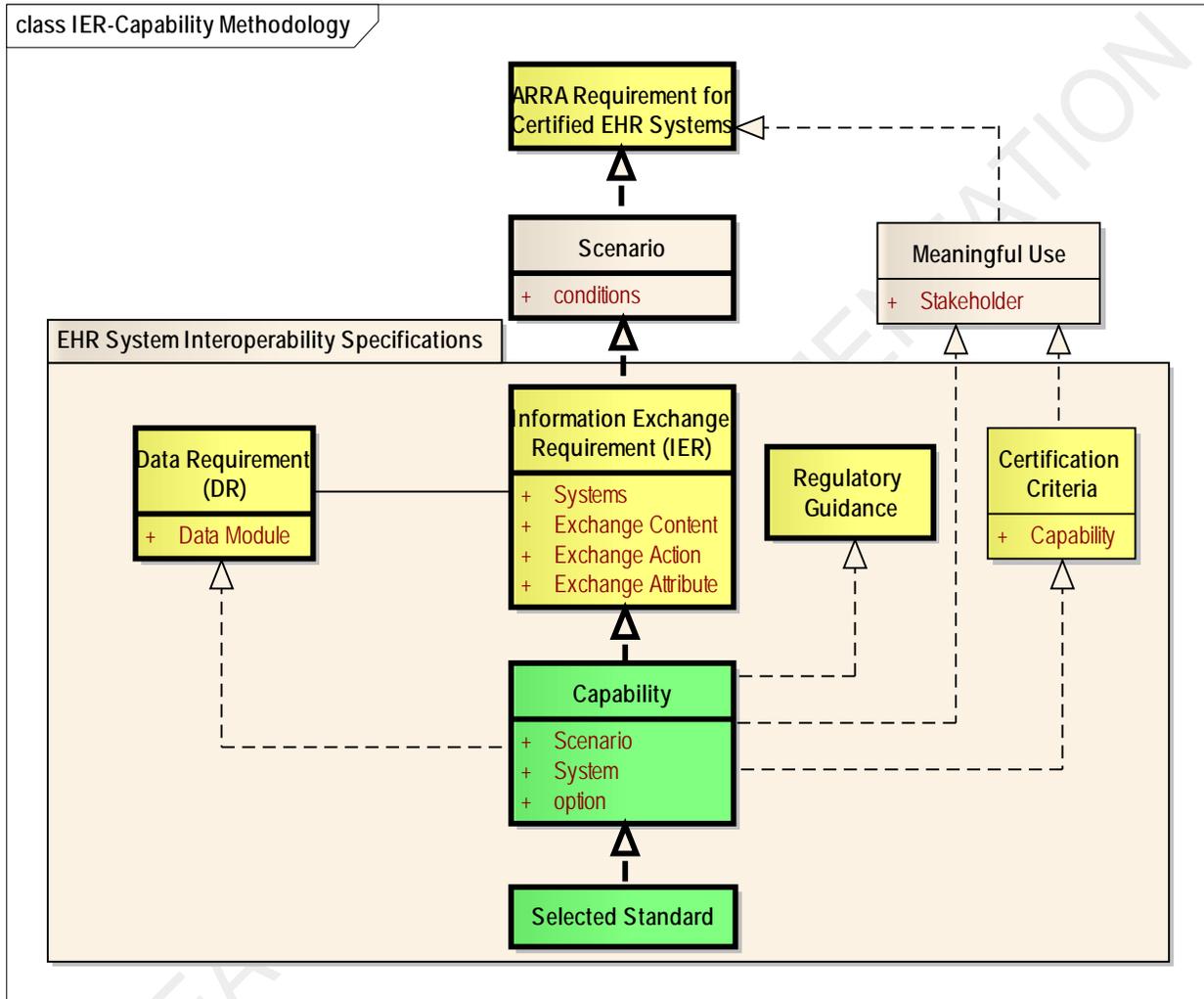
Figure 4-7 HITSP Information Exchange Requirements (IERs) shows that an IER is defined by its set of Exchange Content (EC), Exchange Action (EA), initiating and responding Systems and Exchange Attributes. An Information Exchange is defined as a pair of one or more ECs and an EA. Scenarios help to define the Exchange Attributes' conditions (e.g., context). Stakeholder IERs and DRs define the System Capabilities' requirements. Exchange Attributes define the Exchange Attributes conditions and metadata (e.g., message or document header information) needed for the Design Specification discussed below.

**Figure 4-7 HITSP Information Exchange Requirements (IERs)**
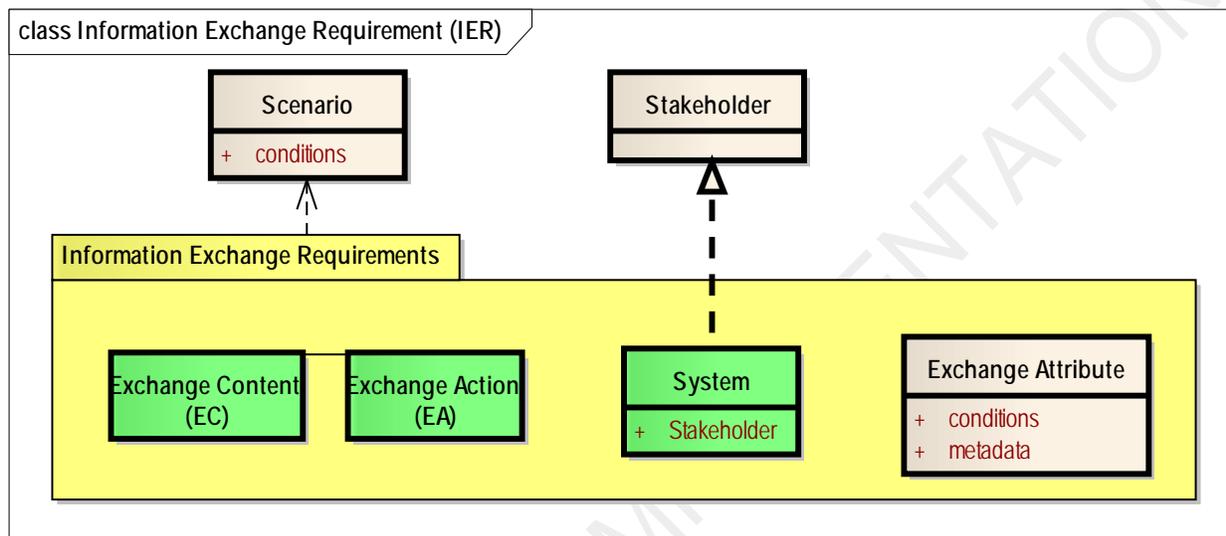
Table 4-2 Sample IER Table shows how the concepts represented in Figure 4-7 HITSP Information Exchange Requirements (IERs) are documented in a HITSP IS. HITSP constructs fulfill their IERs with a standardized value set of reusable Exchange Content, Exchange Action and System facets. Additionally, there is a one-to-one mapping of Exchange Content to HITSP Components (e.g., clinical summary documents) or HITSP Transactions (e.g., referral authorization messages) and a one-to-many mapping of Exchange Actions to HITSP Transactions, Transaction Packages or Service Collaborations.

An Exchange Attribute may include conditions, constraints, message envelope metadata, etc.. Ideally there is a clear boundary established between the message envelope metadata and the payload data. Unfortunately, it is common to have payloads that include so-called envelope data (metadata) that is unique and specific to the payload and which is essential in order for the "real" business transaction to be processed by the appropriate application. Thus, there can be layers upon layers of message envelopes, etc. Implementation specifications must clearly establish the boundaries and use terms and concepts that everyone clearly and consistently understands. These terms must be specific to a given message envelope, such as boundaries like:

- Transport (TCP/IP – HTTP)
- Message (SOAP+WSDL, MIME Multipart, other)
- Payload (X12 interchange which includes the X12 envelope or control structures: ISA/GS/ST)
- Business transactions (the data in-between the X12 ST/SE control structures or envelope)

In summary, for clarity and comprehension, when referring to a message envelope metadata we must clearly use one and only one term to explicitly identify which message and which envelope is currently under discussion.

The IER number and IER short description is local to an Interoperability Specification for the convenience of referencing among IS tables. An example of local numbering and naming is illustrated in a HITSP/C32

Summary Documents Using HL7 Continuity of Care Document or HITSP/C48 Encounter Document Using IHE Medical Summary (XDS-MS); "Clinical Summary" is first constrained to demographics and problem list and then constrained to demographics and medication list. These two local IERs might have local names of "Problem List" and "Medication List" rather than both being ambiguously called "Clinical Summary".

Table 4-2 Sample IER Table

IER # (Local to IS)	IER Name (Local to IS)	Exchange Action[5]	Exchange Content	What System initiates this exchange?	What System (s) responds to this exchange?	Exchange Attribute
IER015	Blood Report	Send	Blood Lab Report	Laboratory Information System	1. PHR System 2. EHR System 3. Public Health Information (PHI) System	Pseudonymize to PHI System
IER016	Specimen Report	Send	Specimen Lab Report	Laboratory Information System	1. PHR System 2. EHR System 3. Public Health Information (PHI) System	Pseudonymize to PHI System

IER Rules:

1. Information Exchange Requirement must consist of at least two systems, one exchange action, at least one exchange content and may have Exchange Attributes
2. Information Exchanges have one system as the initiator and one or more systems as recipients or responders
3. Information Exchanges Content maps to one-or-more Data Requirements (DR)
4. Information Exchanges may have one or more attributes or qualifiers
5. Systems, Exchange Actions, Exchange Contents, DRs and Qualifiers each have identifiers and are maintained in a HITSP registry for reuse and consistency across HITSP documents. IERs are not maintained in a registry
6. An Exchange Action must map to a Transaction(s), Transaction Package or Service Collaboration (one-to-one or many-to-one)
7. DRs map to Data Modules (e.g., in clinical document sections or in message segments from HL7, X12, NCPDP, etc). Data Requirements and Data Modules are more abstract than Data Elements (**DE**s) but a "set" of DEs can fulfill a DR
8. Exchange Contents map to Component(s) (one-to-one or many-to-one)

4.4.1.2 DATA REQUIREMENT

Figure 4-8 Data Requirements shows that the Requirements from a Harmonization Request are analyzed in a Harmonization Request IS and documented as IERs and DRs. Each DR has a 1:1 correspondence

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[5] HITSP Scope includes "Exchange Actions", which are typically the culmination of (prior) predicate Actions. For example: 1) an order is placed; 2) allergies, interactions and contraindications are checked; 3) order is verified; 4) Event/Action scheduling is requested as ordered; 5) resources (equipment, locations, supplies, medications) are requested as ordered; 6) order is transmitted to one or more systems. From HITSP's perspective only Action 6 is an "Exchange Action" and thus considered or documented in the IS. In the preceding example, each predicate Action 1-5 captures essential information and each is likely evidenced by a persistent entry in the EHR. HITSP ISs ignore these EHR-Centric Event/Actions and thus do not reflect data capture, flow and transition prior to (and typically as input to) Exchange Actions. HITSP ISs also ignore the integrity relationship between persistent EHR entries and what is interchanged between EHR (and other) systems. A simple approach to resolving this gap is to record the predicate (e.g., pre Information Exchange) action; but, this does not achieve harmonization. A more comprehensive harmonization approach is to also standardize the EHR information/data model to assure full EHR semantic interoperability, throughout its lifecycle.

with a Data Module specified within a HITSP Component Construct and is associated with the Exchange Content of an IER. Data Modules can be realized by Components or the content of transactions. Also see Table 4-3 Sample IS Data Requirement Table.

Figure 4-8 Data Requirements
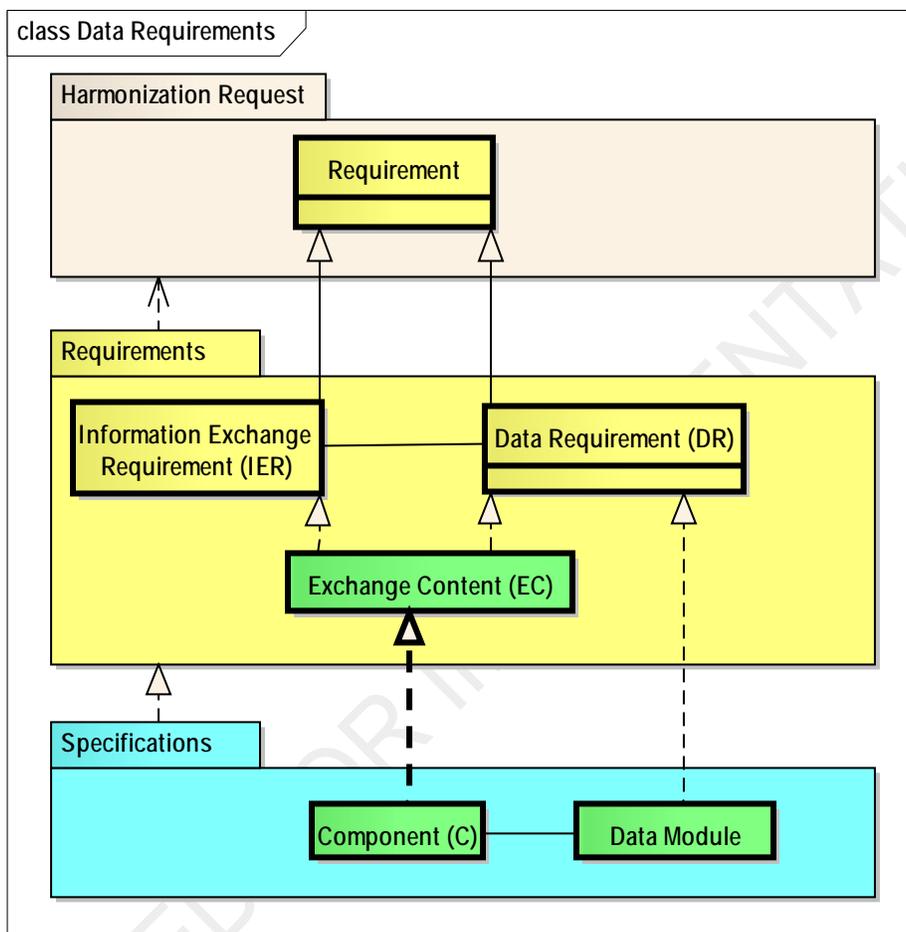
Table 4-3 Sample IS Data Requirement Table

| Exchange Content Number	Exchange Content Name	Definition of the Exchange Content	Data Requirements
EC001	Genomic Decision Support Data	Information from genetic/genomic knowledge sources and/or decision support modules within EHRs (including Fx Hx and Test Results)	DR1 Demographic Data DR3 Clinical History DR4 Personal genetic/genomic data DR5 Family genetic/genomic information DR8 Unstructured Data

4.4.1.3   CAPABILITY

Capability: is an implementable business service that specifies interoperable Information Exchanges using HITSP constructs. A Capability supports stakeholder requirements and business processes and includes workflow, information content, infrastructure, security and privacy.

Figure 4-9 Capability Associations shows the capabilities relationship of HITSP artifacts to the ARRA requirements as HITSP's approach to developing the EHR System Interoperability Specification to fulfill ARRA Requirements.

Figure 4-9 Capability Associations
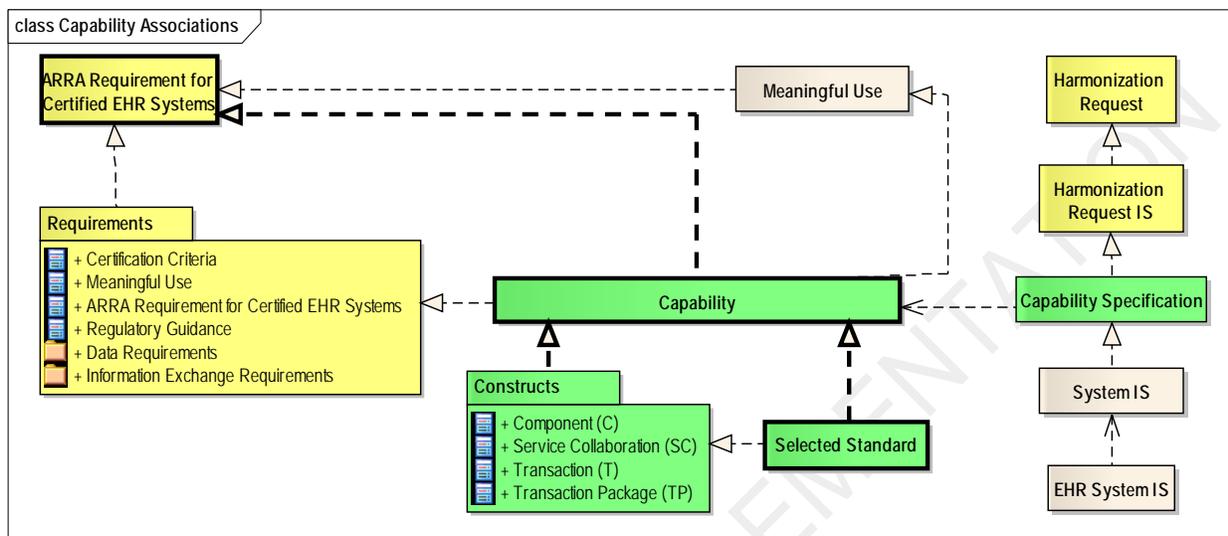
A HITSP Capability is in the interoperability Design Specification space between Systems.

- In the HITSP IS Requirements Section, a Capability fulfills a named set of requirements needed to generate a desired outcome. (e.g., IERs and DRs to exchange lab reports)
- In the HITSP IS Design Specifications Section, a Capability is a named set of constrained HITSP constructs, which specify the selected standards needed to generate a desired outcome. (e.g., HITSP constructs, associated subsets or constraints and their selected standards to exchange lab reports)
- The Implementation of a System supporting a specific Capability is conformant if its interface meets the Capability's design specifications (with the possibility of some options which may be in-or-out) (e.g., HITSP conformant system Capability for the exchange of Lab Reports has an interface, which can be tested to meet the exchange of Lab Report IERs using HITSP system interface specification)

4.4.2 CAPABILITY SPECIFICATION

Figure 4-10 Capability Specification shows a Capability's Design Specification as the mapping of constrained HITSP Constructs to the IERs (e.g., Systems, Exchange Content (EC), Exchange Actions (EA) and Exchange Attributes) described in the Requirements section.

Figure 4-10 Capability Specification
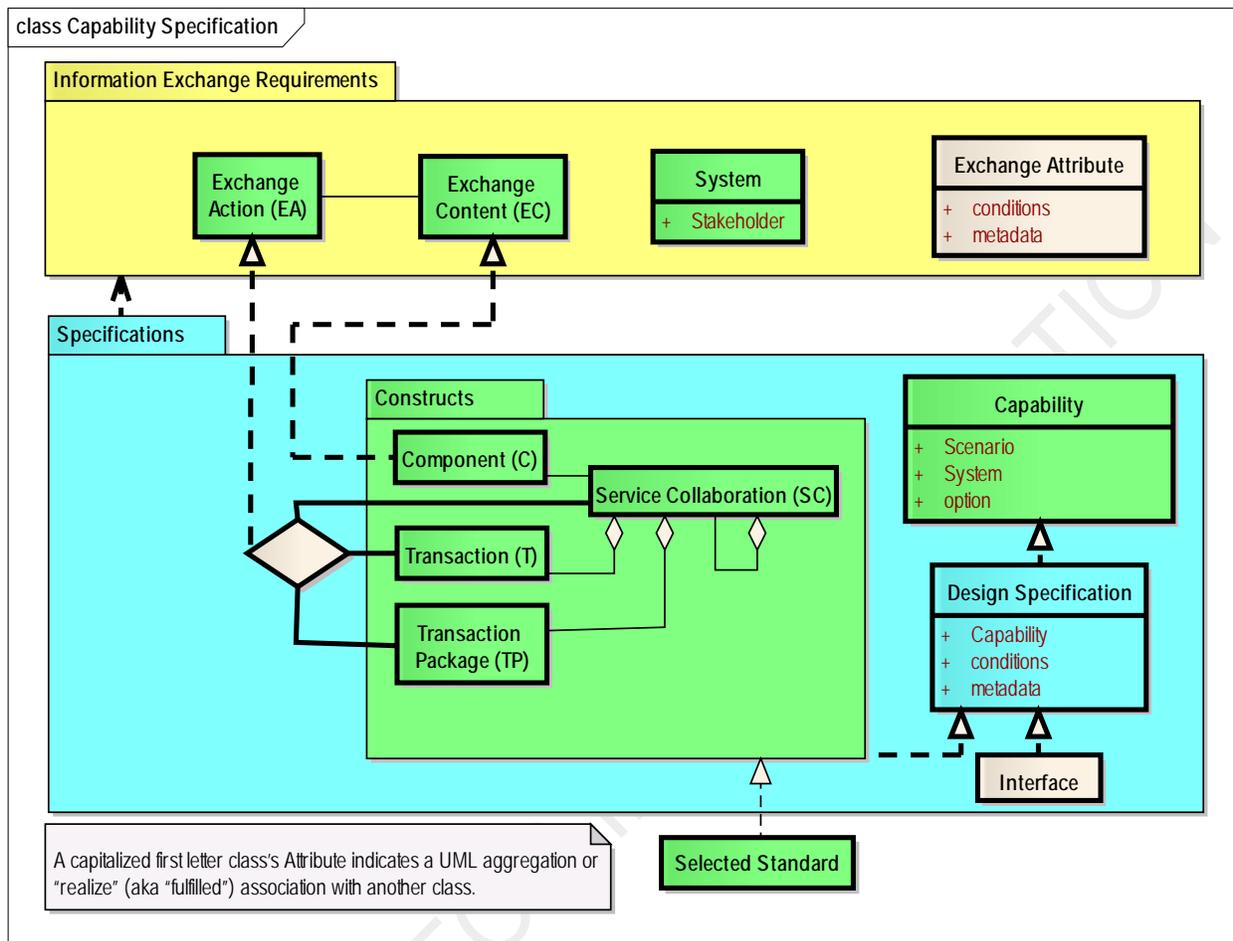
4.4.2.1   SERVICE COLLABORATION

Service Collaboration A Service Collaboration is the composition of HITSP Transaction, Transaction Package, or Component constructs into a reusable workflow, primarily at the infrastructure level. Service Collaborations do not contain content, i.e., Data Elements. Service Collaborations are organized into an external view, i.e., outward facing interfaces, and an internal view that includes inward facing interfaces. Inward facing interfaces may call upon Transaction Packages, Transactions, Components, or other Service Collaborations. The Service Collaboration document illustrates one internal view diagram and sequence table for each service interface. The internal view diagrams are descriptive and the associated sequences are not mandatory. They may be affected by policy, chosen architecture, and implementation details. Conformance is measured against the underlying constructs. Security and Privacy constructs are incorporated into the infrastructure Service Collaborations as appropriate. Figure 4-11 SC Orchestration of Ts, TPs, Cs and other SCs shows how an SC provides reusable support to a Capability.

**Figure 4-11 SC Orchestration of Ts, TPs, Cs and other SCs**
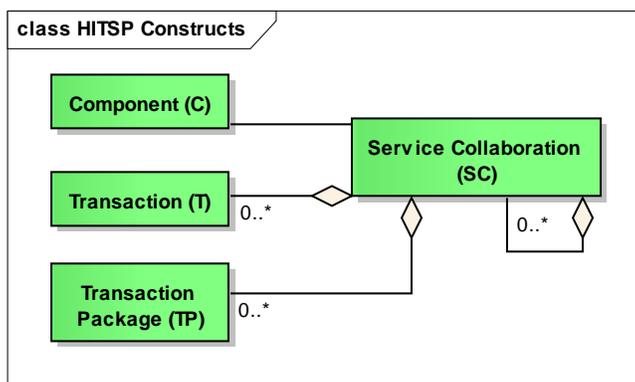
The HITSP constructs within an SC can be atomic (e.g., Transaction), other composite constructs (e.g., Transaction Package or Service Collaborations), or a combination.

- Security and privacy is a property of a Service Collaboration; not a Capability; but many capabilities use Service Collaborations
- SCs only contain Exchange Actions (EAs)
- SCs generally have an associated Exchange Content (ECs)
- Part of the results of an SC may be realized while other parts are not
- SCs may be composed from other SCs
- A SC enforces encapsulation; it has an external specification (e.g., black box specification) and may have one or more implementation examples (e.g., white box description)
- Conformance shall not apply to SCs; but, to the underlying constructs

4.4.3 SYSTEM IS

Figure 4-12 System IS shows the simplicity of a System IS. In its simplest form, it lists the capabilities within a system and references the appropriate Capability Specifications. A self-contained System IS may duplicate the Capabilities' Requirements-Specifications within the document, as was done with the HITSP EHR Centric Interoperability Specification (IS107).

Figure 4-12 System IS
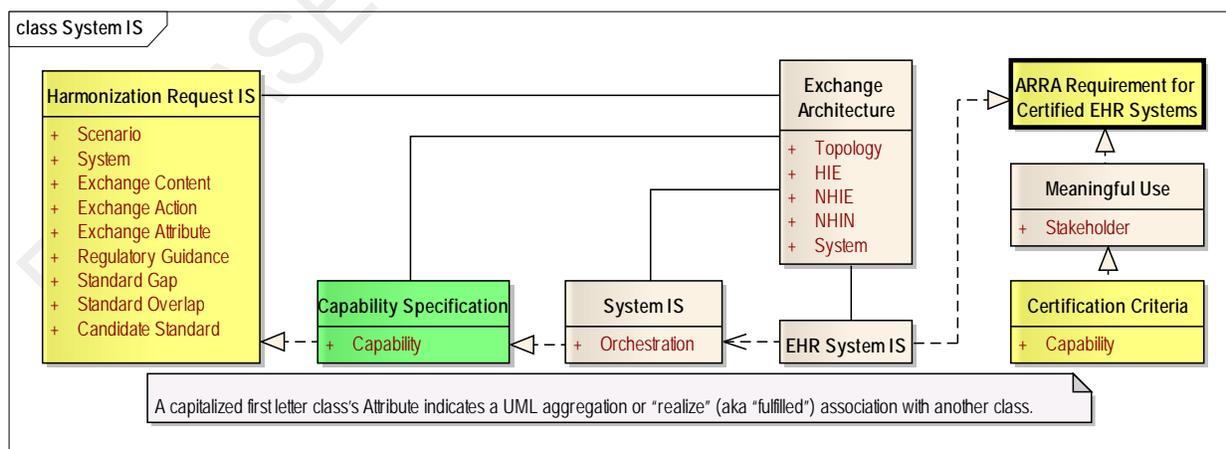
4.5 HITSP HARMONIZATION FRAMEWORK MODEL

This section provides a representation of the HITSP domain using UML class diagrams, which shows key HITSP concepts and their relationships in Figure 4-13 Model of HITSP Harmonization Framework. Figure 4-1 UML Class Diagram Legend shows the UML conventions used in the model. Note that **Bold dashed lines** indicate the key traceability links, which are discussed in Section 4.5.2.

Figure 4-13 Model of HITSP Harmonization Framework
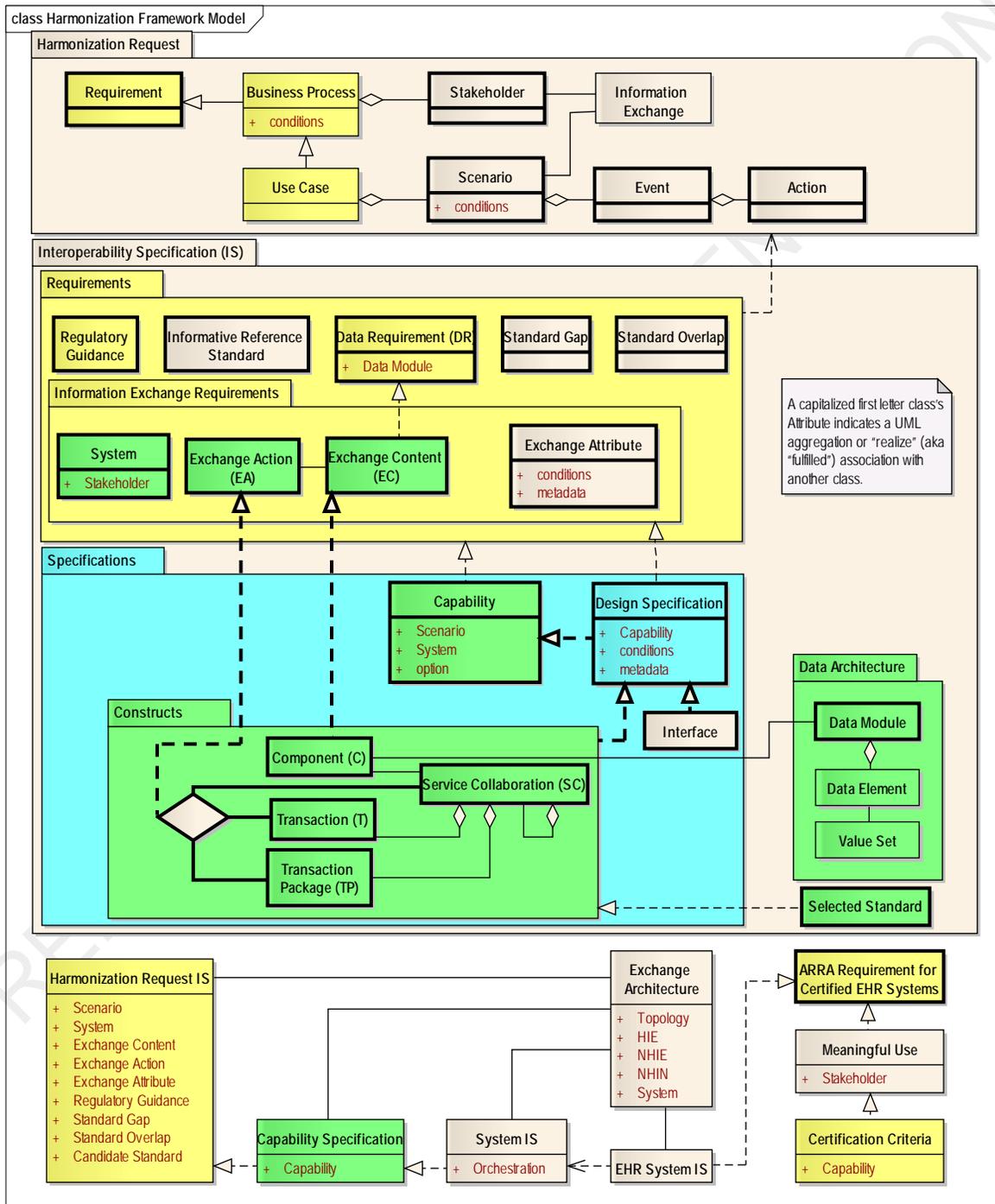
4.5.1 WALK THROUGH OF THE HITSP HARMONIZATION FRAMEWORK

This section can be used by the reader not familiar with UML notation to read the Model of HITSP Harmonization Framework diagram (hereafter called the: Diagram) or to validate the reader's interpretation of the Diagram. This section can be skipped by those comfortable reading the Diagram directly.

The following written explanation of the Diagram should be read with a copy of the Diagram next to it, so as to use the written explanation as a guide through the Diagram or the reverse. These elements and their relationships define both the external and internal building blocks used to produce the Elements. It also depicts how these elements and relationships trace to and support one another.

This explanation explains the UML elements and their relationships in the Diagram. First in an overview summary named the General Structure of the Framework. This is followed by a brief second section which lists rules for determining a deeper understanding of the relationships. This second section is named the Detailed Structure of the Framework.

4.5.1.1 GENERAL STRUCTURE OF THE FRAMEWORK

In UML format, this Diagram shows how the Framework is built by using the elements and the element relationships defined in this document. There are two types of UML elements used on the Diagram. One is called a class and shaped like a box, e.g., Requirement at the top of the Diagram. The second type is called a package and is shaped like a file folder, e.g., Harmonization Request at the top of the Diagram.

In the textual description that follows, the Diagram is read from top to bottom, left to right. The Diagram is divided into 4 parts. Each part consists of elements (packages and/or classes) that are named and then their relationships explained.

There are three organizing parts to the Diagram which are:

1. Harmonization Request which is a package
2. Interoperability Specification (IS) which is a package
3. A part consisting of 8 classes named Harmonization Request IS, Capability Specification, System IS, Exchange Architecture, EHR System IS, ARRA Requirement for Certified EHR System, Certification Criteria and Meaningful Use

4.5.1.2 PART 1 OF THE DIAGRAM DEFINES THE PACKAGE HARMONIZATION REQUEST

These are the eight classes (boxes) at the top of the Diagram shown within the package (file folder) named Harmonization Request. This package consists of:

- Requirement(s) include the Stakeholder's Scenarios' conditions, which is used within Information Exchange Requirement (IER) Exchange Attributes
- Business Process is a type of Requirement
  - Use Case is a type of Business Process
- Use Case is a Business Process description
  - A Use Case has one or more Scenarios
- Stakeholders use Systems to exchange information
- Scenarios are contained within Use Cases
  - Scenarios contain Events
  - Scenarios define the Stakeholders' Requirements for Information
- Information is used by Stakeholders within a Business Process, described by Scenarios
- Event is contained in Scenario, and sets the conditions of the Scenario
  - Events contain Actions
- Action provides the context for a Stakeholder's information exchanges

4.5.1.3   PART 2 OF THE DIAGRAM DEFINES THE PACKAGE INTEROPERABILITY SPECIFICATION (IS)

This Interoperability Specification package consists of three packages named (1) Requirements, (2) HITSP Data Architecture (3) Specifications and one class named Selected Standard:

- The package named Requirements, which depends on Harmonization Request, consists of five classes and one package
  - The class named Data Requirement (DR) which gives the requirements for the IER's Exchange Content (EC)
  - The class named Regulatory Requirement, which is prescribed by law or policy
  - The class Informative Reference Standard, which is optional
  - The class Requirement Gap identifies where HITSP Constructs do not yet exist
  - The class Standard Overlap, where standards harmonization is required.
  - The package named Information Exchange Requirement (IER) contains 4 classes:
    - System fulfills Stakeholder
    - Exchange Action (EA) is fulfilled by Service Collaboration (SC) or Transaction (T) or Transaction Package (TP)
    - Exchange Content (EC) requirements are given by Data Requirement, it is fulfilled by Component (C)
    - Exchange Attributes is defined by the Requirements of Scenario's conditions, it describes the metadata needed by the Design Specifications
- The package named HITSP Data Architectures and consists of three classes:
  - Data Module contains Data Element; Data Module has a 1:1 relationship with Exchange Content
  - Data Element uses Value Set, it is contained by Data Module
  - Value Set is used by Data Element
- The package named Specification consists of one package named HITSP Constructs and three classes named Capability, Design Specifications and Interface:
  - The class named Interface fulfills Design Specifications
  - The class named Design Specifications
    - fulfills IERs
    - fulfills Capability with Constructs, conditions, metadata and an Interface
  - The class named Capability
    - fulfills Requirements by specifying the conditions and metadata for the Capability's Interfaces
    - is fulfilled by Design Specifications and defines Interface Options
  - The package named HITSP Constructs fulfill Design Specification and consists of four classes:
    - Component (C) fulfills Exchange Content (EC), and may be associated with Service Collaboration (SC) and is associated with Data Module
    - Transaction (T) fulfills Exchange Action (EA), it may be contained by Service Collaboration (SC)
    - Transaction Package (TP) fulfills Exchange Action (EA), it may be contained by Service Collaboration (SC)
    - Service Collaboration (SC) may contain other Service Collaborations, it contains Transaction or Transaction Package, it may have an associated Component

4.5.1.4   PART 3 OF THE DIAGRAM DEFINES EIGHT CLASSES

- Harmonization Request IS is realized by the package named Capability Specification

- Capability specification is realized by the package named System IS, and fulfills the Requirements defined in Harmonization Request IS
- System IS is fulfilled by Capability IS and provides the orchestration for the Capabilities
- EHR System IS depends on System IS for its content
- Exchange Architecture is associated with Harmonization Request IS, Capability IS, System IS and EHR System IS
- ARRA Requirements for Certified EHR System is fulfilled by EHR System IS and is fulfilled by Meaningful Use
- Meaningful Use, which is being defined by the Federal Health IT Committee
- Certification Criteria, which traditionally has been defined by the Certification Commission for Health IT (CCHIT).

4.5.1.5   DETAILED STRUCTURE OF THE FRAMEWORK

The detailed structure of the relationships among the classes and packages can be determined by following two rules:

- The relationships between the different classes and the packages are labeled as follows:
    – A bold dashed line is read with the verb "fulfills" and hence is the name of the relationship between any two elements in the Diagram
    – In any other relationship (non-bold dashed line), the default UML relationship name applies, given in Figure 4-1 UML Class Diagram Legend except for Normal UML convention has lower case class attributes
    – Normal UML convention has lower case class attributes. To reduce diagram clutter, the NON UML convention of "a capitalized first letter class's Attribute indicates a UML aggregation or "realize" (aka "fulfilled") association with another class" (e.g., a design realizes or fulfills its requirements). This allows an architectural implementation instance to use object inheritance or delegation
- Refer to Figure 4-14 Traceability to HITSP Interoperability Specifications and note that the relationship labels are numbered "T xx, where xx is a number". These Txx numbers are listed in the first column in Table 4-4. From this table the reader can further determine the relationship table name and its contents

4.5.2   TRACEABILITY OF MODEL TO HITSP IS SECTIONS AND TABLES

Traceability can be shown from:

- Harmonization Request to
- Derived Requirements to
- Capabilities
- Capability's Design Specification, which define the appropriate use of the required
- HITSP constructs and their
- Selected Standards

Figure 4-14 Traceability to HITSP Interoperability Specifications is mapped in Table 4-4 Traceability to HITSP Interoperability Specifications

Figure 4-14 Traceability to HITSP Interoperability Specifications
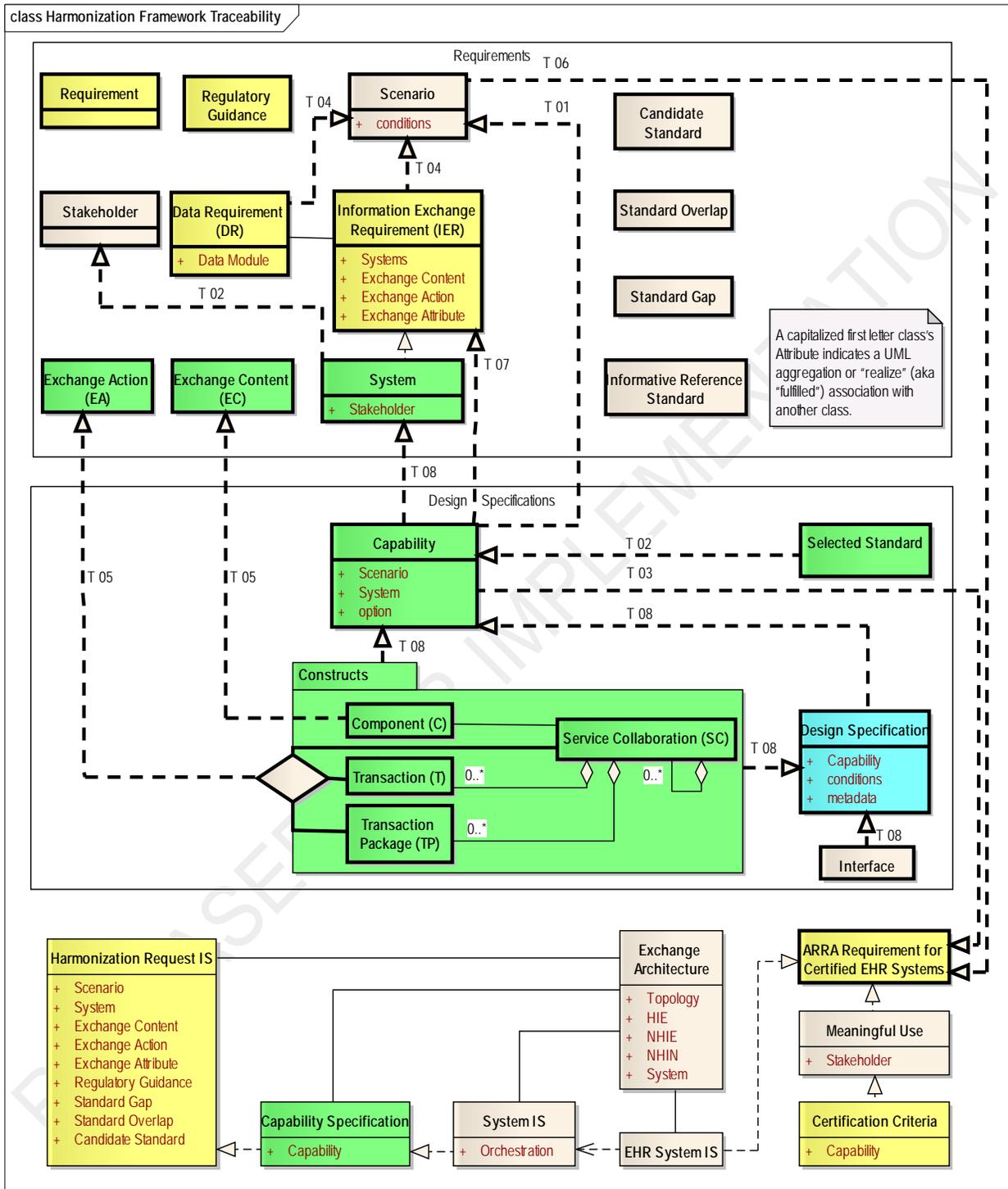
Table 4-4 Traceability to HITSP Interoperability Specifications

Entity	Complete IS	Harmonization IS	Capability Specification	System IS	Description (Bolded Table name: column name, ...)
Scenario	Table 2.1-1	Table 2.1-1		Appendix 5.0	**Description of Scenarios:** Scenario Name, Description
T 05			Table 2.0-1		**Information Exchanges Mapped to Constructs:** Exchange Content, Exchange Action, T/TP/SC used to realize, C used to realize; T/SC/C Optionality/Condition
T 05			Table 2.0-2		**Conditions and Optionality:** Condition/Option Code; description
Capability				Table 2.1-1	**Information Exchange Capabilities:** Capability ID, Capability Name, Capability Description
T 03				Table 2.1-2	**Capabilities mapped to ARRA Requirements:** Capability Name, ARRA Requirement Objective
					Capabilities mapped to Security, Privacy & Infrastructure:
T 02	Table 2.2-1	Table 2.2-1			**System map to Stakeholders:** System Name, System Description, Stakeholders
T 04	Table 2.2-2	Table 2.2-2			**Harmonization Request Analysis:** Event, Action, IER, Initiating System, Responding Systems, Exchange Attribute
Requirement	Table 2.2-3	Table 2.2-3			**Requirements Analysis:** Functional Requirements, IERs, DRs
IER	Table 2.2-4	Table 2.2-4			**Information Exchange Requirements:** IER #, EA, EC, Initiating System, Responding Systems, Exchange Attributes
T 07	Table 2.2.1-1	Table 2.2.1-1			**<Scenario Name> Capabilities mapped to IERs:** Capability, IER Satisfied, Exchange Attributes
Exchange Attributes	Table 2.2.1-2	Table 2.2.1-2			**Conditions:** Conditions, Type of Conditions
Exchange Content	Table 2.2.1-3	Table 2.2.1-3			**Exchange Content:** EC#, EC Name, EC Definition, DR, Conditions
EC GAPS	Table 2.2.1-4	Table 2.2.1-4			**Gaps in Exchange Content:** DR #, DR Name, Data Modules
System • Capability	Table 2.2.2-1	Table 2.2.2-1			**Capability Orchestration:** System, Capability, Conditions
System • Capability				Table 2.1-1	**Capabilities List:** Capability ID, Capability Name, Capability Description

Entity	Complete IS	Harmonization IS	Capability Specification	System IS	Description (Bolded Table name: column name, ...)
System	Table 3.1-1	Table 3.1-1		Table 3.1-1	**Interacting Systems**: Interacting Systems
ARRA Requirement					See T 03
Design Specification • conditions	Table 3.1.3.1-1		Table 3.1.3-1	Table 3.1.3.1-1	**Conditions**: Conditions, Type of Conditions
Design Specification • constructs	Table 3.1.3.2-1			Table 3.1.3.2-1	**List of Constructs**: Construct, description
T 08	Table 3.1.3.3-n N=1, 2, ... for each system			Table 3.1.3.3-1	**<Capability Name> Interoperability Specification**: Interface (Initiating or Responding), interface #, interface condition, T, TP, SC or Content, T, SC, Content Optionality
Design Specification • capability	Table 3.1.3.3-2			Table 3.1.3.3-2	**<Capability Name> Implementation Conditions**: Condition Code, Condition Description Condition Code = <capability #>-[101] ...
Design Specification • options	Section 3.1.3.4				**Capability Options**
Regulatory Guidance	Table 4.1.1	Table 4.1.1			**Regulatory Guidance**: List of Regulations
T 02	Table 4.1.2-1	Table 4.1.2-1			**Selected Standards Linked to HITSP Capabilities**: Standard, Capability, Remarks/Minor Gaps
Informative Reference Standards	Table 4.1.3-1	Table 4.1.3-1			**Informative Reference Standards**: Standard
Requirements Gaps	Table 4.2-1	Table 4.2-1		3.1.3.5-1 (not to be published, a parking lot)	**Use Case Requirements and Associated Standards Gaps**: Requirement #, Summary Description, Identified Gap Recommended Resolution
Standards Overlaps	Table 4.3-1	Table 4.3-1			**Use Case Requirements and Associated Standard Overlaps**: Requirement #, Summary Description, Standard Overlap, Recommended Resolution
T 01				Appendix 5.1	Capability mapped to IS Scenario
T 06				Appendix 5.1	**IS/Scenarios Mapped To Arra Requirements**: ARRA Section Ref, Hitsp ARRA Req. #, Short Name, ARRA Text, IS/Scenario #
					HITSP Capabilities Mapped To The HITSP Provider, Population And Consumer Interoperability Specifications
					HITSP Capabilities Mapped To HITSP TP50 Through TN 901

5.0 HITSP EXCHANGE ARCHITECTURE EXAMPLES

This section provides definitions and examples (e.g., instances) of the HITSP Exchange Architecture. Since a HITSP Capability is in the interoperability space between Systems, an instance of an Exchange Architecture can be represented as a table or diagram of system entities connected by their capabilities' interfaces.

Exchange Architecture: defines the fundamental topologies that can be used in implementing the HITSP Interoperability Specifications in systems (e.g., EHR systems connected to independent Health Information Exchanges (HIEs) and HIEs connected to the NHIE or directly connected.

5.1 SCOPE

This section presents examples (e.g., instances) of the HITSP Exchange Architecture, as defined in the Harmonization Framework. A separate excel spread sheet and/or database, available at www.hitsp.org, contains the value sets of the HITSP Exchange Architecture set of Exchange Actions, Exchange Content, Systems, and their mapping to the 13 legacy 2008 Interoperability Specification (**IS**) Information Exchange Requirements (**IER**s). Figure 3-6 Notional Exchange Architecture Topologies shows the Exchange Architecture concepts introduced in the Harmonization Framework. An instance of an Exchange Architecture adds topology to the Harmonization Framework

5.2 EXCHANGE ARCHITECTURE EXAMPLES

HITSP Exchange Architecture instances are a simplified way to describe or specify:

- Capabilities
- Interoperability Specifications (IS) or their scenario
- Implementation Architectures
- Deployment Architectures

First we show simple notional examples of how instances of the Exchange Architecture might be represented. Except for Figure 5-3 Simple PPT "Exchange Clinical Summary" Capability Exchange Architecture, the diagrams follow the conventions shown in Figure 5-1 UML Component Diagram Legend. After Figure 5-1 UML Component Diagram Legend, this section shows how an Exchange Architecture is used in an Interoperability Specification.

- Figure 5-2 Simple UML "Exchange Clinical Summary" Capability Exchange Architecture
- Figure 5-3 Simple PPT "Exchange Clinical Summary" Capability Exchange Architecture

These methods are extensible to a multitude of specification and implementation Exchange Architecture instances.

- HITSP/IS09 Consultations and Transfers of Care was used because it represents two typical clinical situations in a simple topology
- HITSP/IS04 Emergency Responder Electronic Health Record was used as a complex example, where topology is essential to its scenarios

An Exchange Architecture table, such as Table 5-1 HITSP/IS09 Capabilities Applicable to Consultations and Transfers of Care Systems might be useful in describing an instance of the HITSP Exchange Architecture for a particular specification and/or implementation.

Note that a variety of modeling styles are used in this section to illustrate modeling alternatives in representing an Exchange Architecture. The connectors might be labeled to represent:

- Capabilities

- Information Exchange Requirements (IERs)
- Data Requirements (DR)
- Exchange Content (EC)
- Exchange Action (EA)
- Individual System Data Exchanges

Figure 5-1 UML Component Diagram Legend
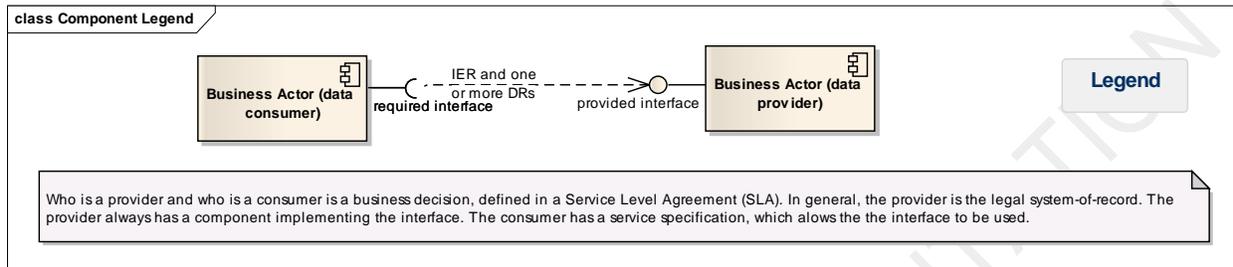
Figure 5-2 Simple UML "Exchange Clinical Summary" Capability Exchange Architecture should be compared to the increasingly complex

- Figure 5-3 Simple PPT "Exchange Clinical Summary" Capability Exchange Architecture
- Figure 5-4 HITSP/IS09 Consultations and Transfers of Care Notional Exchange Architecture
- Figure 5-5 Notional HITSP/IS04 ER-EHR Exchange Architecture (showing different labeling styles)

Note that various numbering conventions are used to label the Information Exchanges. Numbers may correspond to the capability number or the interfaces within the capability (e.g., 1-1 "Exchange Clinical Summary" using HITSP/TP13 Manage Sharing of Documents, while 1-2 might be "Exchange Clinical Summary" using HITSP/T63 Emergency Message Distribution Element – OASIS EDXL). Effectively this separates Exchange Content and Exchange Actions. These choices represent different levels of abstraction, which might be used to describe the Exchange Architecture. One might label the connections with the highest business level of abstraction as capabilities. Considering that there are approximately 26 capabilities and larger numbers of IEs, ECs and EAs, this will minimize the clutter in the diagram and also correspond to business needs. The cleanest approach is to not label the Information Exchanges; but rather, rely on the associated tables to provide fidelity to the generic Exchange Architecture diagram(s).

**Figure 5-2 Simple UML "Exchange Clinical Summary" Capability Exchange Architecture**
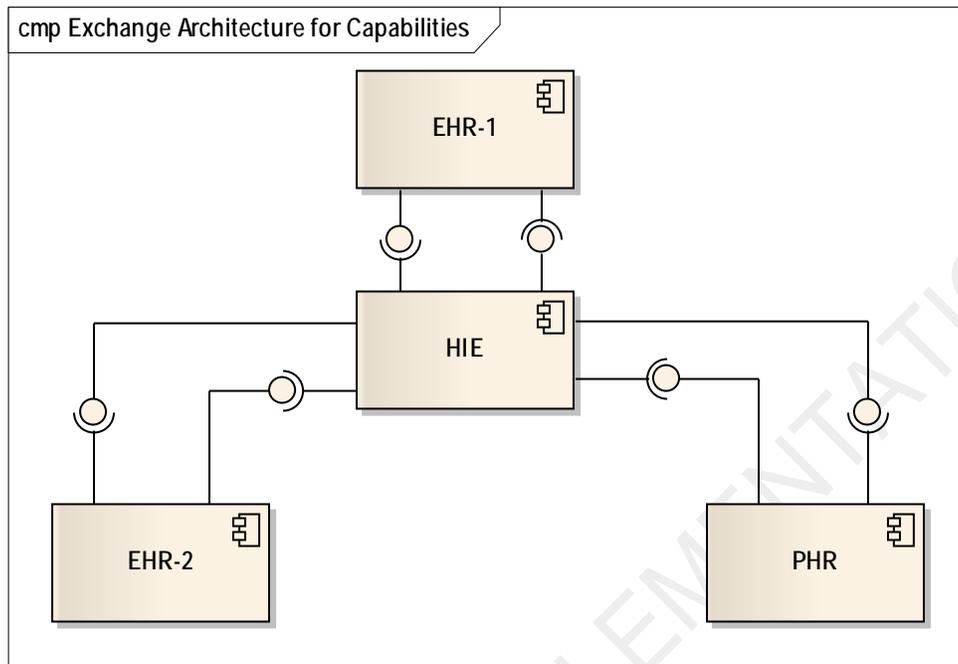
Figure 5-3 Simple PPT "Exchange Clinical Summary" Capability Exchange Architecture
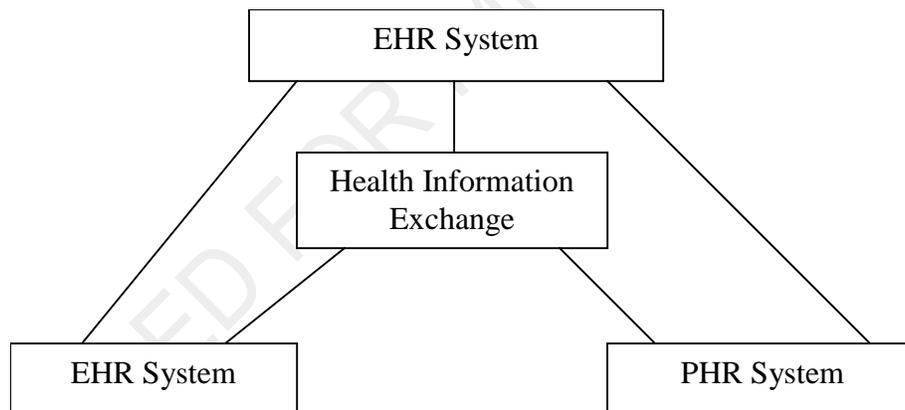
5.2.1 HITSP/IS09 CONSULTATIONS AND TRANSFERS OF CARE EXAMPLE

The HITSP/IS09 Consultations and Transfers of Care (CTC) describe the information flows, issues and system capabilities that apply to:

- A provider requesting and a patient receiving a consultation from another provider
- A provider requesting a transfer of care for a patient and the receiving facility admitting the patient

It is intended to facilitate access to information necessary for consultations and transfers for consulting clinicians, referring clinicians, transferring facilities, receiving facilities and consumers.

5.2.1.1 EXCHANGE ARCHITECTURE

Since a HITSP Capability is in the interoperability space between Systems, an instance of an Exchange Architecture can be represented as a table or diagram of system entities connected by their capabilities'

interfaces. Figure 5-4 HITSP/IS09 Consultations and Transfers of Care Notional Exchange Architecture assumes a simple point-to-point topology of communications. To make this example simple, the three capabilities of Clinical Operations, Quality and Public Health and Administrative and Financial are used.

Table 5-1 HITSP/IS09 Capabilities Applicable to Consultations and Transfers of Care Systems

System	Clinical Operations	Quality and Public Health	Administrative and Finance
Health Plan			X
Infrastructure Services	X	X	X
Provider Administrative & Financial			X
Decision Support	X	X	X
EHR	X	X	
PHR/HRBs	X	X	
Laboratory Information Systems (LIS)	X	X	X
Diagnostic Imaging Service Provider	X		X

Figure 5-4 HITSP/IS09 Consultations and Transfers of Care Notional Exchange Architecture
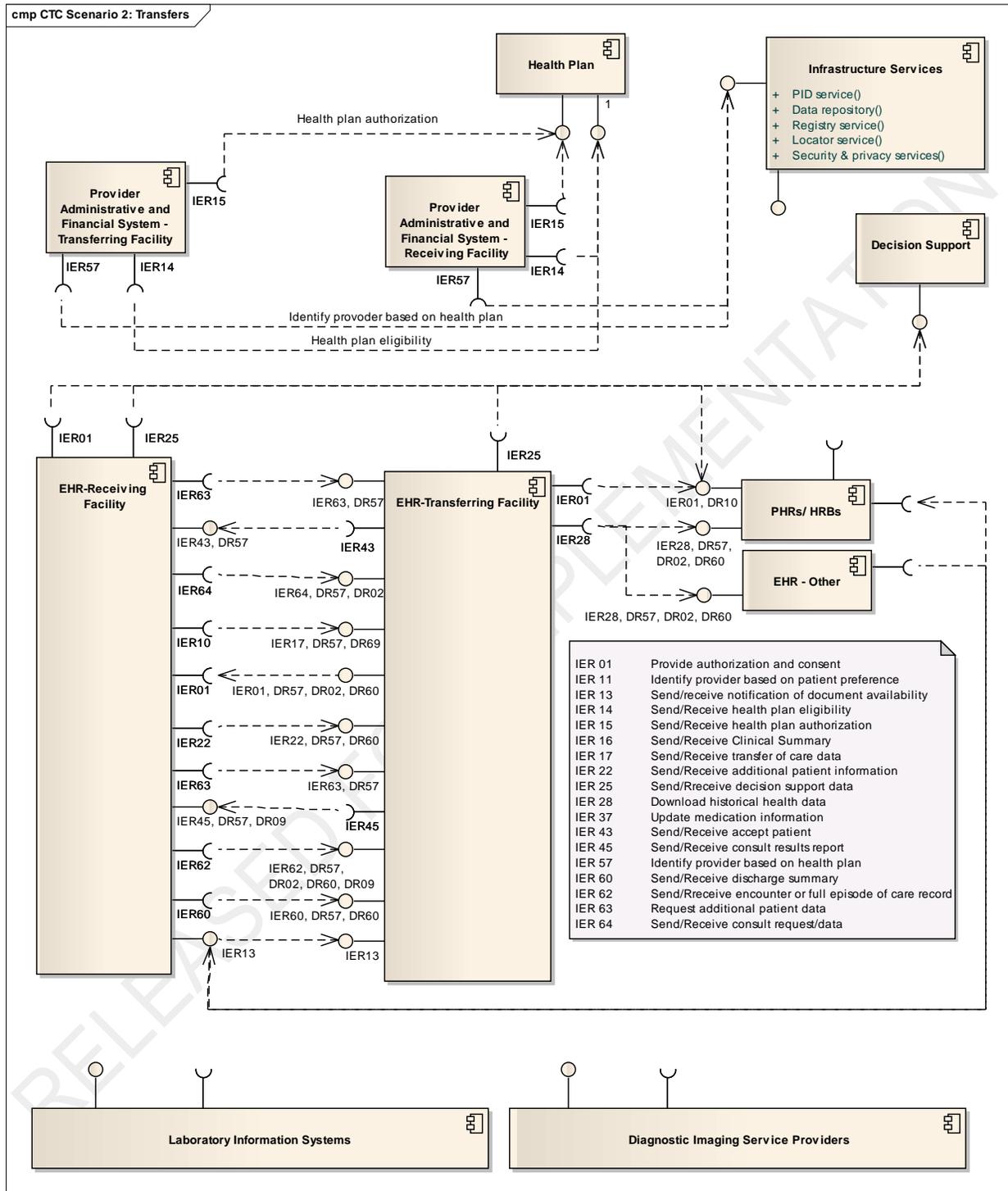
5.2.2 HITSP/IS04 EMERGENCY RESPONDER ELECTRONIC HEALTH RECORD EXAMPLE

HITSP/IS04 Emergency Responder Electronic Health Record (ER-EHR) describes the information flows, issues and system capabilities that apply to:

- On-site care (IS04 Scenario 1)
- Emergency Care (IS04 Scenario 2)
- Definitive Care (IS04 Scenario 3)
- Common Process: Provider Authentication and Authorization

5.2.2.1 EXCHANGE ARCHITECTURE

The ER-EHR Exchange Architecture assumes a complex combination of point-to-point and HIE topologies. It portrays an incident in a rural area, served by a regional EMS, hospital and ancillary services which are interacting with National services as shown in Figure 5-5 Notional HITSP/IS04 ER-EHR Exchange Architecture (showing different labeling styles).

Assuming the same high level capabilities as was used in HITSP/IS09 Consultations and Transfers of Care, we can create Table 5-2 HITSP/IS04 Capabilities Applicable to ER-EHR Systems. Capabilities per system can be specified at an appropriate high or low level of detail.

Table 5-2 HITSP/IS04 Capabilities Applicable to ER-EHR Systems

System	Clinical Operations	Quality and Public Health	Administrative and Finance
EHR	X	X	
LIS	X	X	X
HIE	X	X	X
CPOE	X		
DSS	X	X	X
NHIE	X	X	X
PHS		X	
Financial System			X
PHR	X		

Figure 5-5 Notional HITSP/IS04 ER-EHR Exchange Architecture (showing different labeling styles)
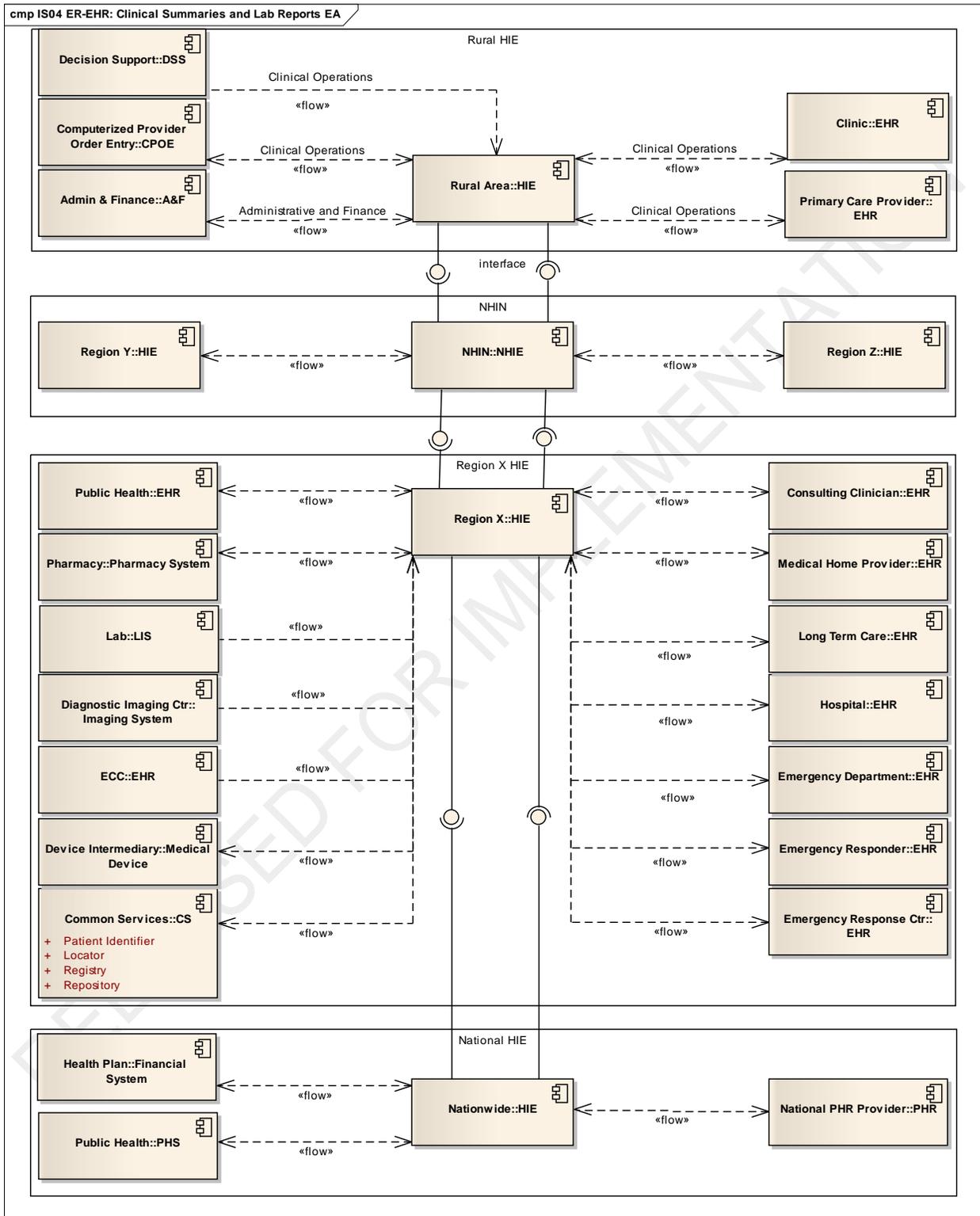
6.0 STANDARDS TYPES AND CATEGORIZATION

This section will cover the definitions for types of references in HITSP Constructs. HITSP has identified 3 categories in which a standard may be used in a construct:

- Regulatory Guidance
- Selected Standard
- Informative Reference

In each category, standard references must be precise and unambiguous. They should indicate the specific version and/or other release-specific information as well as effective dates where applicable.

6.1 COMPOSITE AND BASE STANDARDS

6.1.1 BASE STANDARD

Base Standard is a standard capable of fulfilling a discrete function within a single category produced and maintained by a single standards organization. Per HITSP definition, the term "standard" refers to, but is not limited to, specifications, Implementation Guides, code sets, terminologies and Integration Profiles. Examples are messaging standards, security standards and code sets.

6.1.2 COMPOSITE STANDARD

Composite Standard is a grouping of coordinated base standards, often from multiple standards organizations, maintained by a single organization. Specific to HITSP, a composite standard can serve as a Component, Transaction or Transaction Package. Examples are functional requirements, Integration Profiles, Implementation Guides and health transaction services.

6.2 SELECTED STANDARDS

The HITSP Harmonization Framework defines a set of artifacts, known as "constructs", that:

- specify how to integrate and constrain selected standards to meet the business needs and
- define a roadmap to use emerging standards and harmonize overlapping standards when resolved

Selected standards have gone through the HITSP Tier-2 process that evaluates competing standards. It is a standard that is necessary for interoperability. The standard is required to meet Information Exchange requirements of the construct (e.g., to realize direct Information Exchange, provide the transport mechanism, specify the content or to address security).

6.3 REGULATORY GUIDANCE

Regulatory guidance is a legal or other authoritative mandate which HITSP must follow in the design of a construct. Examples of regulatory guidance are:

- The Health Insurance Portability and Accountability Act (HIPAA)
- Clinical Laboratory Improvement Amendments (CLIA)
- Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003

6.4 INFORMATIVE REFERENCES

An informative standard is a standard that provides additional background information or guidance and is not required to implement the specification.

7.0 USE DECLARATIONS WITHIN A SELECTED STANDARD

This section discusses the values that can be assigned to data elements within a standard.

7.1 USE DESIGNATIONS AND DEFINITIONS

Within a standard, especially in those that define the "payload" of an exchange, a number of declarations can be made about the presence of the data elements (CDA XML or message fields, Components or sub-Component delimiters) as well as about the content of the data elements. The basic values and definitions that can be applied with a standard are:

- **R = Required** - Required data elements must always be sent. Data elements that are required may under exceptional circumstances have an unknown value (e.g., not knowing the name of an unconscious patient). In these cases the sending application is required to indicate the reason that the data are not available (this may be through a null value that has predefined semantics)
- **R2 = Required if known** - If the sending application has data for the data element, it is required to populate the data element. If the value is not known, the data element need not be sent

The R2 designation is an IHE addition to the HL7 values of R (Required), O (Optional), and C (Conditional) that recasts the intent of the RFC2119 keywords SHOULD and RECOMMENDS. The intent is clearly stronger than Optional, but recognizes universal support may not be feasible in some instances. However, the decision to not support an R2 identified element should be made with awareness that there are consequences that can prevent interoperability. This value is used with CDA XML documents as the technology supports the dynamic nature of the payload.

- **RE = Required but can be empty** – if the sending application has the data it must send it; if not the data element must be supported but can be empty
    - This is found in HL7 Messaging standards. This is the message equivalent of the R2 value, but given that non-xml messaging implementations cannot handle dynamic structures the sender and receiver must support the presence of the field delimiters and content, even if they cannot supply it or use it.
- **O = Optional** - Data elements that are marked optional (O) may be sent at the choice of the sending application. An optional element need not be sent, but when it is sent, the content module defines the meaning of that data element and a receiver can always be assured of what that data element represents when it is present. Senders should not send an optional data element with an unknown value. If the value is not known, simply do not send the data element[6]

Note that the use of these values is reflected in conformance statements and as test criteria.

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[6] HL7 V3 null value might imply that data may be available later or "masked" means the sender has it; but, chooses not to send it or pending authorization.

8.0 INDEX

9.0 DOCUMENT UPDATES

The following sections provide the history of all changes made to this document.

9.1 JUNE 30, 2009

No changes. This is the first published version of the document.

9.2 JULY 8, 2009

Upon approval by the HITSP Panel on July 8, 2009, this document is now Released for Implementation.